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STATEMENT OF DAVID H. REMES, ESQ.
COVINGTON & BURLING
ON BEHALF OF THE TOBACCO INSTITUTE

BEFORE THE

STATE OF MARYLAND
DEPARTMENT OF LICENSING AND REGULATION
MARYLAND OCCUPATIONAL SAFETY AND HEALTH
ADVISORY BOARD

December 9, 1993

My name is David Remes. I am a lawyer with Covington & Burling in Washington. We are counsel to The Tobacco Institute, a trade association of major cigarette manufacturers. I have with me today several distinguished experts:

- Patrick R. Tyson, Esq., a former high-ranking official of the U.S. Occupational Safety and Health Administration. Mr. Tyson will explain why the proposed regulation would not satisfy the applicable requirements of the Maryland Occupational Safety and Health Act.

- Gio Batta Gori, Ph.D., a health policy consultant who is President of the International Society of Regulatory Toxicology and Pharmacology. Dr. Gori will address the shortcomings of the Environmental Protection Agency's recent report on environmental tobacco smoke from a scientific standpoint.

- Steven C. Parrish, Esq., General Counsel and Senior Vice President, External Affairs, Philip Morris U.S.A. Mr. Parrish will discuss the lawsuit brought by the tobacco industry challenging the EPA's classification of ETS as a Group A carcinogen. Mr. Parrish also will make clear why we believe that the EPA report is primarily a political, not a scientific document.

- Simon Turner, Director of Healthy Buildings International, a company which has been studying and evaluating indoor air quality in buildings all over the world for over a decade. Mr. Turner will provide an overview of how ETS fits in with the overall issue of indoor air quality.

We oppose the proposed regulation banning workplace smoking.

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In addition to the points that will be made by the other witnesses, we believe that it is inappropriate for the Board to consider a workplace smoking standard. As our written comments explain, the U.S. Occupational Safety and Health Administration is the appropriate agency to address workplace smoking. Action by the Board at this time would be premature and wasteful and would raise serious questions under the U.S. Occupational Safety and Health Act (as well as under Maryland's Occupational Safety and Health Act). In addition, a regulation banning smoking in the workplace would amount to an end-run around the Maryland Legislature.

Unlike other matters considered by the Board, a regulation banning smoking in the workplace would broadly restrict personal employee behavior and would have wide social implications. Smoking is an established social custom of long standing. Over 25 percent of all adult Americans -- 50 million Americans -- smoke. Despite the efforts of antismoking activists to make it seem otherwise, smoking is not a socially deviant behavior. And smoking is a behavior that is not limited to employees. Customers, visitors and other nonemployees who might be present in a workplace smoke, too.

Public smoking has been the subject of extensive consideration by the Legislature. The Maryland Legislature has enacted laws prohibiting and restricting smoking in a number of

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places.[1/] In 1990, 1991 and 1992 bills were introduced to address smoking in workplaces and other public settings. The Legislature declined to act, leaving the issue for private resolution. This past September, the Environmental Affairs Committee of the House of Delegates held an oversight hearing at which it received extensive testimony in preparation for considering additional legislation in 1994.

What the Board is being asked to do today is to step in and legislate, even as the Maryland Legislature is preparing to consider the matter again to determine what action may be warranted in the future. The Board should not allow itself to be used to do an end-run around the Legislature.

I also would like to address briefly the suggestion that the Board should ban smoking in the workplace to protect employers from liability claims by nonsmokers under state workers' compensation and tort law or the Americans with Disabilities Act of 1990. As discussed in the statement submitted by The Tobacco Institute today, and in the statement submitted by Victor Schwartz to the Environmental Matters Committee in September, the decided cases make clear that employers need not

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1/ The Legislature has prohibited or restricted smoking in buses (Md. Ann. Code art. 78, § 35A), retail stores (Md. Health-Gen. Code Ann. § 24-502), hospitals (Md. Ann. Health-Gen. Code Ann. § 24-205), mass transit (Md. Ann. Transp. Code Ann. § 7-705), fireworks plants (Md. Ann. Code art. 38, § 23) and public elevators (Md. Ann. Code art. 89, § 64). In addition, the Governor has prohibited smoking in state buildings by Executive Order. Exec. Order No. 01.01.1987.13.

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ban smoking to minimize the risk of claims by -- and liability to -- nonsmoking employees.

For employers, the key is a policy that provides employees with an adequately ventilated working environment and does not force objecting nonsmokers to share their immediate workspace on a sustained basis with smoking colleagues. Most employers today do attempt to accommodate their nonsmoking employees -- that is, they do not require objecting nonsmokers to share their immediate workspace on a sustained basis with smoking colleagues.

The Americans with Disabilities Act does not mandate smoking bans to accommodate employees claiming hypersensitivity to ETS. As noted by an official of the U.S. Equal Employment Opportunity Commission, "the ADA does not require employers to have a smoke-free environment or prevent it. It does not interfere one way or the other." Moreover, the ADA's accessibility guidelines assume that restaurants will be able to provide smoking and nonsmoking sections for their customers. And in Harmer v. Virginia Electric & Power Co., a federal district court in Virginia recently rejected an employee's claim that the ADA mandated a smoke-free work environment. The court's decision in this case follows the decisions of other courts under the parallel provisions of the federal Rehabilitation Act.

I would like to submit for the record a copy of Mr. Schwartz's statement to the Environmental Affairs Committee.

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David H. Remes received his B.A. from Columbia College in 1976 and his law degree from Harvard in 1979. He has been at Covington & Burling since 1983. He specializes in Legislation and Constitutional law.

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December 1, 1993

VIA FEDERAL EXPRESS

Maryland Occupational Safety
and Health Advisory Board
501 St. Paul Place
Baltimore, Maryland 21202

Re: Draft Prohibition on Smoking in the Workplace

Honorable Members of the Board:

I am respectfully enclosing the comments of Philip Morris Companies, Inc. regarding the above-referenced matter. We appreciate the opportunity to comment in this proceeding and look forward to participating in the rulemaking process.

Our submission consists of one volume of comments and 32 volumes of reference materials. The comments volume contains the following:

1. Overview;
2. Brief in Opposition to the Draft Prohibition;
3. Summary Analysis -- Environmental Tobacco Smoke: The Scientific Issues of Exposure and Health; and
4. Summary Analysis of Selected Responses to Federal OSHA's Request for Information on Occupational Exposure to Indoor Air Pollutants.

We have enclosed 15 copies of the comments volume, as requested in the hearing notice.

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The reference volumes consist of two sets, one containing scientific data underlying the Summary Analysis entitled "Environmental Tobacco Smoke: The Scientific Issues of Exposure and Health" and the other containing selected responses to federal OSHA's Request for Information on Occupational Exposure to Indoor Air Pollutants. Because of the large amount of reference materials included in our submission, Maryland Assistant Attorney General Elaine Patrick suggested that we submit only one copy of those volumes. According to Ms. Patrick, the reference volumes will remain on file at the Division of Labor and Industry where they may be reviewed by individual Board members upon request. We would also be happy to provide copies of particular reference materials to individual Board members upon request.

In addition to our written submission, we intend to testify before the Board at its public hearings later this month. We look forward to this opportunity to address the Board in person.

We are firmly committed to working in a constructive and cooperative manner with the Board and the Commissioner in this proceeding. We believe that if the Board is presented with all relevant factual data and if it views the data completely and fairly, it will be in the best possible position to make an equitable decision.

Philip-Morris Companies, Inc. is the largest consumer packaged goods company in the world. Its subsidiaries include Philip-Morris U.S.A., the largest cigarette company in the United States; Philip-Morris International, the leading United States exporter of cigarettes; Kraft General Foods, the largest processor and marketer of packaged grocery, coffee, cheese and processed meat products in the United States; and Miller Brewing Company, the second largest brewing company in the world. These companies produce brand name products such as *Maxwell House, Sanka, Jell-O, Post, Kool-Aid, Marlboro, Entenmanns, Kraft* cheeses, *Parkay* margarine, *Oscar Mayer, Louis Rich, Breyers, Birds Eye, Cool Whip, Miller High Life* beer, and *Lite* beer. Total employment is approximately 168,000, of which approximately 100,000 workers are employed in the United States.

The Company's interests in this rulemaking are twofold: (1) as an employer with over 500 employees and 12 facilities in the State of Maryland, and (2) as the largest manufacturer and exporter of cigarettes in the United States. Because of our size and diversity, we have considerable knowledge and experience with respect to both of these interests. We, therefore, offer the assistance of that technical experience and expertise, both as employers who own and manage a wide variety of buildings and with

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respect to the issue of the effects of environmental, or as we will reference it in our submission, passive tobacco smoke (PTS).

We recognize the complexity and sensitive nature of the PTS issue. We know that many people may find smoking objectionable. In fact, we reflect that knowledge in smoking policies covering our own employees. In these policies, we acknowledge the rights of all employees, and encourage the accommodation of both smokers and non-smokers through tolerance, common sense, and courtesy. When this is unsuccessful, supervisors are responsible for accommodating the preferences of each employee.

As the Board undertakes its consideration of this complex issue, we urge its members to do so in a fair and impartial manner, and not to allow issues of personal preference or bias to color their scientific and technical judgment. We have been thoughtful and sincere in our preparation of this submission. We have not attempted to mislead the Board or urge it to adopt positions that are not well supported by a fair interpretation of the relevant data. We trust and hope that each Board member will view the evidence objectively.

Sincerely,

Patrick R. Tyson

Patrick R. Tyson
Attorney for Philip Morris Companies, Inc.

PRT/dls
Enclosures

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Before the
Maryland Occupational Safety & Health Advisory Board

IN RE:	Draft Prohibition on Smoking in the Workplace	§ § § §	COMAR No. 09.12.23

Overview

Dated:
December 1, 1993

Respectfully Submitted By:
Philip Morris Companies, Inc.
120 Park Avenue
New York, NY 10017-5592

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OVERVIEW

I. INTRODUCTION

On December 9 and December 16, 1993, the Maryland Occupational Safety and Health (MOSH) Advisory Board will hold hearings on an initial draft of a proposed regulation that, if enacted, would ban employee smoking in all workplaces. The proposed regulatory language provides that "[a]n employer shall ensure that an employee, while in the place of employment, does not smoke." The term "smoke" is defined to mean "use or carry any lighted pipe, cigar, cigarette, or other tobacco product in any form." Philip Morris is opposed to this ban. It is Philip Morris' position that such a ban is not authorized by law, is not adequately supported by science, and is unduly burdensome on both employers and employees. This Overview statement is intended to provide the Advisory Board with a non-technical summary of (1) the legal prerequisites to promulgating such a regulation, (2) the lack of scientific data supporting a ban on smoking in the workplace, and (3) the adverse effects on employers and employees resulting from a workplace ban on smoking. We have also submitted additional documents which provide more detail and support for statements that we make in this Overview.

Philip Morris respectfully requests that the Advisory Board reconsider this proposed regulation.

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II. LEGAL PREREQUISITES TO REGULATION

A. Absence of Significant Risk

The MOSH Act provisions regarding the adoption of safety and health standards that regulate "toxic materials or harmful physical agents" are modeled, almost verbatim, on the federal Occupational Safety and Health (OSH) Act. A side-by-side comparison of the MOSH Act and federal OSH Act provisions regarding promulgation of occupational safety and health standards reveals how closely the MOSH Act mirrors the federal OSH Act in this regard:

MOSH Act	Federal OSH Act
The Board shall ". . . recommend occupational safety and health standards that most adequately ensure, to the extent feasible on the basis of the best available evidence, that no employee, including an employee who has regular exposure to toxic materials or harmful physical agents during the working life of the employee will suffer material impairment of health or functional capacity."	The Secretary of Labor shall ". . . set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life."
§ 5-309(c)(1)	29 U.S.C. § 655(b)(5)

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Similarly, both the federal OSH Act [29 U.S.C. § 652(8)] and the MOSH Act [§ 5-101(e)] define "occupational safety and health standard" as a regulation that requires a condition, or the adoption or use of practices, means, methods, operations or processes, that are reasonably necessary or appropriate to provide safe and healthful employment and places of employment.[1]

While there is no case authority under Maryland law interpreting the threshold requirements that must be met under the MOSH Act before regulation of workplace exposures can occur, the corresponding federal OSH Act language has been extensively interpreted by the federal courts, including the United States Supreme Court. When this situation has occurred with other Maryland laws, Maryland courts have consistently followed the federal courts' interpretations. The leading federal case on the promulgation of occupational safety and health standards is Industrial Union Department, AFL-CIO v. American Petroleum Institute, 448 U.S. 607 (1980) (Benzene). In that case, the United States Supreme Court struck down OSHA's attempt to reduce the permissible exposure limit (PEL) for benzene from 10 ppm to 1 ppm, as well as the Agency's ban on dermal contact with benzene. OSHA's regulatory policy at the time of the Benzene decision was that whenever the toxic material to be regulated was a carcinogen, there was a presumption that there was no safe level of exposure. 448 U.S. 624 N.19. OSHA admitted, however, that it lacked the scientific data necessary to demonstrate the relationship between a particular exposure level and the risk of cancer associated with that

[1] The MOSH Act uses the phrase "reasonably appropriate or necessary" while the federal OSH Act uses the phrase "reasonably necessary or appropriate."

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level of exposure. 448 U.S. 631-632. In rejecting this regulatory policy, the Court held that OSHA had failed to demonstrate with substantial evidence that benzene exposure at or below the former PEL of 10 ppm (and above the new 1 ppm PEL) posed a significant risk of material health impairment. 448 U.S. at 631-634.

The importance of the Benzene decision in the present consideration of a ban on smoking in the workplace is that the Supreme Court held that before issuing a standard to regulate a toxic material or harmful physical agent, the Secretary of Labor must establish that the exposure to such a toxic material or harmful physical agent makes the workplace unsafe for employees. The Court very clearly explained that requiring that a workplace be safe is not the same as requiring that it be risk-free. 448 U.S. at 650. A workplace is considered to be unsafe only if the workplace exposures threaten employees with a significant risk of harm. Therefore, before promulgating any occupational safety and health standard, the language of the statute requires a threshold finding that the place of employment is unsafe in the sense that the toxic substance in question poses a "significant risk of material health impairment." 448 U.S. at 642.

In addition to establishing the existence of a significant risk, the Secretary must also demonstrate that the proposed standard is "reasonably necessary or appropriate" to reduce the risk.[2/] This step in the analysis necessarily requires some assessment or determination of the level at which the significant risk of harm is eliminated or substantially reduced. 448 U.S. 662. In the Benzene decision, the Supreme Court struck

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[2/] OSHA must also show that the standard is economically or technologically feasible. Obviously, if a standard is not feasible, it is not "reasonably necessary or appropriate."

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down OSHA's ban on dermal contact with benzene, because OSHA did not show the ban to be "reasonably necessary and appropriate" to remove a significant risk of harm from dermal contact with any level of benzene, no matter how minute the exposure. In sum, the Supreme Court held that a ban on dermal contact could not be justified because there was no showing of the level of exposure at which a significant risk of harm existed, nor that a ban was "reasonably necessary and appropriate" to remove that risk.

Applying the Supreme Court's requirements in the Benzene case to the present consideration of a workplace smoking ban, MOSH must first establish by substantial evidence that workplace exposure to environmental or passive tobacco smoke (PTS)[3] poses a "significant risk of material health impairment." Little reliable scientific data exists on workplace exposure to PTS. More importantly, the data that does exist, fails to support a finding of significant risk. Of the 35 published epidemiologic studies on spousal smoking and lung cancer, 14 assessed reported workplace exposures to PTS. Of these 14 workplace studies, 12 reported associations between PTS and nonsmoker lung cancer which did not achieve statistical significance.[4] (See pages 1-2 of Section B of our

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[3] We are using the acronym "PTS" in this document because federal OSHA used this term in its Request for Information concerning "Occupational Exposure to Indoor Air Pollutants", 56 Fed. Reg. 47892 et seq. (1991). OSHA used the phrase "passive tobacco smoke" so as not to confuse this topic with OSHA's procedure for an "emergency temporary standard" or "ETS."

[4] When a hypothesis (in this case, that there is an association between nonsmoker exposure to PTS in the workplace and lung cancer) is tested, the result is statistically significant if the probability that it occurred by chance is low. The level of statistical significance commonly accepted is expressed in terms of a .05 probability or significance level. "Significant with .05 probability means there is only a 5 percent probability that the results were attributable to chance and a 95 percent probability that the results were attributable to the experiment." Risk Analysis: A Guide to Principles and Methods for Analyzing Health and Environmental Risks, Cohrssen and Covello, U.S. Department of Commerce, National Technical Information Service, 1989, p. 373.

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"Summary Analysis on Environmental Tobacco Smoke: The Scientific Issues of Exposure and Health," included in this volume under Tab 3). Likewise, of the five published epidemiologic studies addressing workplace exposure to PTS and heart disease, none reported a statistically significant increased risk of heart disease among nonsmokers claiming exposure to PTS at work. (See page 3 of Section C of our "Summary Analysis on Environmental Tobacco Smoke: The Scientific Issues of Exposure and Health," included in this volume under Tab 3).

The lack of reliable workplace exposure data is further demonstrated by federal OSHA's response to a lawsuit filed in United States Court of Appeals for the District of Columbia by Action on Smoking and Health (ASH) to force OSHA to issue an emergency temporary standard banning smoking in the workplace. The Secretary of Labor, on behalf of OSHA, conceded that "the data concerning occupational exposure to ambient tobacco smoke was inadequate to permit OSHA to quantify the risk existing under prevailing occupational exposure conditions. There is simply no agreement among scientists as to the likely exposure levels and the degree of risk in workplaces, as distinguished from non-occupational settings." ASH v. OSHA, No. 89-1656 (Brief for the Secretary of Labor, April 5, 1991).

The United States Environmental Protection Agency's (EPA) recent risk assessment on PTS will be repeatedly referenced by individuals and groups supporting a workplace smoking ban. The EPA Report, titled "Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders," focuses primarily on exposure to high levels of passive smoke from spousal smoking in the home. Only 11 of the 30 spousal smoking studies analyzed in the EPA Report even include estimates of workplace PTS exposures in addition to exposure in the home environment, and these estimates provide only very little

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exposure data. Ten of those 11 studies reported no statistically significant increased risk for the non-smoking spouse. And, if the workplace exposure data from all 11 studies were pooled in what is referred to as a meta-analysis, the risk assessment would indicate no positive association between workplace exposure to PTS and lung cancer in nonsmokers.

Moreover, of the 11 United States spousal smoking studies that EPA relies on to estimate the relative risk associated with PTS, none originally achieved statistical significance overall. Only after EPA subsequently lowered the original statistical significance standards used by the authors of the studies was EPA able to reach its conclusion.[5] Furthermore, EPA failed to include in its PTS risk assessment one of the largest and most recent studies on PTS, funded in part by the National Cancer Institute, which reported no overall statistically significant increase in risk between spousal smoking and lung cancer. Had these study data been included in the EPA's risk assessment and analyzed using accepted statistical standards, the overall lung cancer risk estimate from reported PTS exposure would again not have been statistically significant. When the data are properly considered, the EPA's risk assessment does not provide support for a significant risk evaluation in Maryland.[6]

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[5] The authors of these studies used a 95% probability test, which is the standard used by most scientists. The EPA, however, lowered the confidence interval to 90%. If an experiment or test were conducted 100 times, a "95% confidence interval" is a statistical expression of the range of values in which the experiment or test results would fall 95 times out of 100. By lowering the confidence interval, the EPA has increased the likelihood that the results are incorrect.

[6] It should also be noted that the EPA's risk assessment has been challenged in court and that litigation is still pending. Flue-Cured Tobacco Cooperative Stabilization Corporation, et al. v. United States Environmental Protection Agency, et al. Case No. 6:93CV 370 (M.D.N.C. 1993).

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Even if MOSH could establish that any amount of PTS, no matter how minute, poses a risk of material health impairment, the Agency must also demonstrate that the quantity of the risk posed is significant. Although the courts have held that this quantitative risk assessment need not be made with scientific certainty, the Agency must provide at least an estimate of the actual risk associated with exposure to a particular toxic substance and explain why that risk is significant. In its rulemaking processes, federal OSHA has satisfied this requirement by estimating the number of workers likely to suffer the effects of exposure. In the Benzene case, the Supreme Court offered as an example of significant risk, a scenario in which one employee in 1,000 who were exposed to the toxic substance would suffer the expected consequences. Following the Supreme Court's quantification of significant risk, OSHA adopted as its policy that it will only regulate levels of toxic materials or harmful physical agents that pose a risk of at least one excess death per 1,000 employees. Following this policy, to regulate PTS, MOSH would have to demonstrate that current levels of exposure to PTS in the workplace present a risk of at least one excess death per 1,000 employees. The scientific data, when fairly and objectively evaluated, do not support such a finding.

B. MOSH Must Satisfy The "Products Clause"

Assuming for the purposes of argument that MOSH could establish a significant risk of material impairment of health, Section 5-309 of the MOSH Act, which parallels Section 18(c)(2) of the federal OSH Act, states that any standards proposed must be required by "local conditions" and must not put an undue burden on interstate commerce. MOSH cannot establish either condition of this so-called products clause. Since

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Even if MOSH could establish that any amount of PTS, no matter how minute, poses a risk of material health impairment, the Agency must also demonstrate that the quantity of the risk posed is significant. Although the courts have held that this quantitative risk assessment need not be made with scientific certainty, the Agency must provide at least an estimate of the actual risk associated with exposure to a particular toxic substance and explain why that risk is significant. In its rulemaking processes, federal OSHA has satisfied this requirement by estimating the number of workers likely to suffer the effects of exposure. In the Benzene case, the Supreme Court offered as an example of significant risk, a scenario in which one employee in 1,000 who were exposed to the toxic substance would suffer the expected consequences. Following the Supreme Court's quantification of significant risk, OSHA adopted as its policy that it will only regulate levels of toxic materials or harmful physical agents that pose a risk of at least one excess death per 1,000 employees. Following this policy, to regulate PTS, MOSH would have to demonstrate that current levels of exposure to PTS in the workplace present a risk of at least one excess death per 1,000 employees. The scientific data, when fairly and objectively evaluated, do not support such a finding.

B. MOSH Must Satisfy The "Products Clause"

Assuming for the purposes of argument that MOSH could establish a significant risk of material impairment of health, Section 5-309 of the MOSH Act, which parallels Section 18(c)(2) of the federal OSH Act, states that any standards proposed must be required by "local conditions" and must not put an undue burden on interstate commerce. MOSH cannot establish either condition of this so-called products clause. Since

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the alleged health effects of PTS are no different in Maryland than in any other state, MOSH cannot show that "local conditions" in Maryland justify a workplace ban just for that state. Workplace exposure to PTS is clearly national in scope and therefore within the province of federal OSHA, which in fact has already initiated the rulemaking process on the regulation of indoor air quality. 56 Fed. Reg. 47892 et seq. [Docket No. H-122] (1991). Individual state standards, which will inevitably conflict, will certainly unduly burden interstate commerce of tobacco products.

III. INDOOR AIR QUALITY

Concern about indoor air quality and such issues as "sick building syndrome" has been voiced in both private and public employment environments over the last several years. The current smoking ban under consideration in Maryland may, in part, be in response to this concern. While a workplace smoking ban may be viewed by some as an easy solution to inadequate indoor air quality, existing research reveals that PTS has a very minimal effect on the quality of indoor air. Some of the most compelling evidence in this regard comes from the U.S. Department of Labor's National Institute for Occupational Safety and Health (NIOSH). In its summary of the Health Hazard Evaluations that it performs in workplace buildings, NIOSH reports that out of approximately 500 evaluations, 52% of its investigations result in findings that inadequate ventilation is the source of most indoor air quality problems. In a detailed study of 203 of those investigations conducted in 1984, NIOSH reported that tobacco smoke was a contributing factor in only four or 2% of the buildings investigated. In a 1989 follow-up report of over 500 building

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investigations, NIOSH elected not to even designate PTS as a separate category of contributing factors.

In those situations where indoor air quality is regulated, non-smoker exposure to PTS may be significantly reduced in a cost effective manner by adopting ventilation rates such as those specified in the American Society of Heating, Refrigerating and Air Conditioning Engineers (ASHRAE) Standard 62-1989, "Ventilation for Acceptable Indoor Air Quality." ASHRAE Standard 62-1989 establishes minimum ventilation rates for various indoor settings in order to "control carbon dioxide and other contaminants with an adequate margin of safety, and to account for variations among people, varied activity levels, and a moderate amount of smoking." This Standard was approved in 1990 by the American National Standards Institute (ANSI). ASHRAE 62-1989 has been adopted by 12 states and by two major building code organizations in the United States, and is currently under consideration for adoption by the remaining national building code organizations. The Standard recommends a ventilation rate of 20 cubic feet of outside air per minute (cfm) per person for most commercial or office facilities, with 15 cfm as the minimum. The drafters of the Standard concluded that a minimum ventilation rate of 15 cfm/occupant will produce air quality that is acceptable to 70% of visitors and to 90% of occupants, assuming a moderate amount of smoking (30% smoking, 1.7 cigarettes/hour/smoker).

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IV. PRACTICAL EFFECTS OF THE PROPOSED BAN

The proposed workplace smoking ban has other, perhaps unanticipated, implications for both employers and employees in the state. This ban penalizes employees in workplaces where satisfactory measures have been established that accommodate the interests and concerns of both smokers and non-smokers alike. For companies that have created designated internal smoking areas, have permitted smoking in specified outdoor areas, have committed to maintaining adequate ventilation, or whose employees follow a rule of mutual consideration and accommodation regarding smoking, Maryland's proposed ban undercuts these reasonable workplace solutions. At the same time that the proposed ban is adversely affecting the employees in these environments, it is, in effect, turning the employers and MOSH into the "smoking police." The enforcement problems that would accompany a ban of this nature would be further compounded by work sites over which the employer has little control (e.g. taxicabs, trucks, company cars) and by work sites that, by their nature, have more than adequate outside air (e.g. agriculture, construction). For all of these situations, the Maryland proposed ban takes an issue that is currently being satisfactorily addressed in most workplaces through voluntary solutions agreed upon by management, employees and labor representatives and unnecessarily turns it into an issue that infringes upon employee rights and subverts existing workplace accommodations. It would also force the redirection of scarce occupational safety and health enforcement resources.

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V. CONCLUSION

It is the position of Philip Morris that the available scientific data do not support a finding of "significant risk." In the absence of a showing of "significant risk," regulation of PTS and, more specifically, a regulatory ban on PTS, is not legally justifiable. In addition to the legal prerequisites that should be considered by the Advisory Board, Philip Morris also urges the Board to closely consider the practical implications of the proposed ban and the effect it would have on the vast majority of employers who have or are in the process of voluntarily addressing workplace smoking. Finally, if it is determined that a need exists for regulatory action, the Advisory Board should consider the adoption of ventilation rates at least equivalent to those set forth in a general consensus standard like ASHRAE 62-1989. Such a regulation would effectively improve indoor air quality generally and, at the same time, address PTS in the workplace.

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Before the
Maryland Occupational Safety & Health Advisory Board

IN RE:	Draft Prohibition on Smoking in the Workplace	§ § § §	COMAR No. 09.12.23

Brief in Opposition to Draft Prohibition on Smoking in the Workplace

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Dated:
December 1, 1993

Respectfully Submitted By:
Philip Morris Companies, Inc.
120 Park Avenue
New York, NY 10017-5592

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Mr. Bruce C. Bereano, Esq.

December 6, 1993

Greetings. David Remes of Covington & Burling suggested that the enclosed manuscript be sent to you directly, so that sufficient copies can be made for the MOSHAB hearing on December 9th.

See you soon, and all good wishes

With all good wishes.

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ENVIRONMENTAL TOBACCO SMOKE IS NOT A PROVEN OCCUPATIONAL HAZARD

STATEMENT OF GIO BATTA GORI, DSc, MPH

TO THE

MARYLAND OCCUPATIONAL SAFETY AND HEALTH ADVISORY BOARD

DECEMBER 9 , 1993

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SUMMARY

* ETS IS NOT EQUIVALENT TO THE SMOKE INHALED BY SMOKERS. ALTHOUGH GENERALLY BEYOND MATERIAL DETECTION, POSTULATED ETS COMPONENTS WOULD BE ORDERS OF MAGNITUDE BELOW LEVELS OFFICIALLY PERMITTED IN WORKPLACES.

* EPA'S CLAIM THAT ETS IS A LUNG CANCER RISK STEMS FROM THE SELECTIVE AND IMPROPER USE OF EPIDEMIOLOGIC DATA. EPIDEMIOLOGIC REPORTS OF WORKPLACE ETS EXPOSURE DO NOT SUPPORT CLAIMS OF INCREASED LUNG CANCER RISK.

* EPIDEMIOLOGIC STUDIES DO NOT SUGGEST THAT ETS IS A CARDIOVASCULAR RISK FACTOR IN THE WORKPLACE.

* THE SURGEON GENERAL AND OTHERS REPORT NO STATISTICALLY SIGNIFICANT ASSOCIATION OF ETS AND RESPIRATORY DISEASES IN ADULTS.

* EPA'S REPORT ON ETS IS NOT SCIENTIFICALLY JUSTIFIED. IT IS A POLITICAL GAMBIT IN A LONG EPA TRADITION OF BENDING SCIENCE TO SUIT POLICY AIMS.

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My name is Gio Gori. I am a toxicologist with training in epidemiology and broad interests in smoking and health, cancer causation and risk assessment. I am President of the International Society of Regulatory Toxicology and Pharmacology, and Fellow of the Academy of Toxicological Sciences. In the 60's and 70's I was Deputy Director for Cancer Cause and Prevention at the National Cancer Institute, where I received the Public Health Superior Service Award in 1977 for separate activities as Director of the Smoking and Health Program. My resume is appended to this statement.

This statement is presented at the request of The Tobacco Institute. The views expressed, however, are my own and do not necessarily represent the position of The Tobacco Institute.

Recent interest in ETS has been motivated by the report on ETS released by the U.S. Environmental Protection Agency (EPA) on January 7, 1993 (1). Therefore, my comments will address the scientific merits of that report, as well as other data not addressed in the report and contrary to its conclusions.

I shall proceed according to standard scientific criteria of objective verification. Science is the mother of all technological innovations that sustain our civilization. In this role, science has achieved a deserved reputation for objectivity. Scientists seek objectivity by rules similar to the evidentiary rules observed in a court of justice. No effect is assumed until proven, while proof requires direct or indirect involvement, elimination of alibis, reliable witnesses, material evidence, and so on.

In this light, my assessment also rests on the premise that the Maryland Occupational Safety and Health Advisory board (MOSHAB) has an initial and paramount interest in determining how reliable a foundation of fact the Board is dealing with.

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The EPA case rests on the claim that ETS is equivalent to the smoke that smokers inhale, and on the claim that epidemiologic studies of people who report exposure to ETS have a higher risk of lung cancer. The question is then: are these claims independently and objectively justifiable?

ETS IS NOT EQUIVALENT TO THE SMOKE INHALED BY SMOKERS. ALTHOUGH GENERALLY BEYOND MATERIAL DETECTION, POSTULATED ETS COMPONENTS WOULD BE ORDERS OF MAGNITUDE BELOW LEVELS OFFICIALLY PERMITTED IN WORKPLACES.

The EPA itself is not sure that ETS is equivalent to the smoke that smokers inhale, and both asserts and denies this notion in different chapters of the ETS report (1. pages 2-9 and 6-6). Indeed, there are good reasons for its equivocations throughout the report.

ETS derives from the side-stream smoke produced by smoldering cigarettes, and from the small residues of main-stream smoke exhaled by active smokers. Generated and existing under much different conditions, these distinct smokes have some similarities but marked differences in chemical and physical composition and behavior.

Of the several thousand components identified in main-stream smoke, only a few hundred have been detected in side-stream smoke, due to greater dilutions. Because of even more extreme dilutions, fewer than 50 ETS components have been identified directly under field conditions, stretching the sensitivity limits of current analytical capabilities (2,3). Indeed, the compilers of reports from the National Academy of Sciences (4), the US Surgeon General (5) and the Environmental Protection Agency

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(1,6,7) have been forced to infer the presence of ETS components by proxy, based on the composition of side-stream smoke from which ETS derives. However, ETS becomes very much different from side-stream smoke as it ages and undergoes complex chemical and physical transformations by interacting with oxygen, light, and many other environmental components (2-5).

Nominally, then, ETS and mainstream smoke may share some components, but their chemical and physical properties are substantially different, as the National Academy of Sciences has recognized (4). Moreover, the presence of most ETS components can only be postulated because most are beyond material detection, and only around three dozen are analytically traceable to ETS under real life conditions (1-5).

In view of this situation, there is no scientific justification for the regulation of ETS in workplaces on the basis of its comparison with main-stream smoke. Even under the unwarranted assumption that side-stream smoke remains unaltered as it becomes diluted and aged ETS, concentrations of postulated ETS components would be several orders of magnitude below the corresponding PEL or TWA levels permitted in workplaces by the U.S. Occupational Safety and Health Administration (8). Indeed, the EPA report itself presents data suggesting that in the course of an entire year the average nonsmoker may inhale less "tar" than the active smoking of one single cigarette (1,8).

Thus, the vanishing nature of ETS precludes postulating its similarity to main-stream smoke beyond vague conjectures. The Agency's Science Advisory Board itself told EPA's staff that the alleged equivalency of ETS and cigarette smoke could not be sustained (9). Still, EPA's contrived identification of ETS and main-stream smoke was felt necessary to bolster the weak and inconclusive results of ETS epidemiologic studies.

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EPA'S CLAIM THAT ETS IS A LUNG CANCER RISK STEMS FROM THE SELECTIVE AND IMPROPER USE OF EPIDEMIOLOGIC DATA. EPIDEMIOLOGIC REPORTS OF WORKPLACE ETS EXPOSURE DO NOT SUPPORT CLAIMS OF INCREASED LUNG CANCER RISK.

Three categories of exposure can be identified in epidemiologic studies of ETS and lung cancer. One group considers people exposed to ETS at work, and shows no overall increase of lung cancer risk. MOSHAB should be especially interested in this absence of overall risk as it comes from 13 published studies on lung cancer and workplace exposure to ETS, of which 7 were conducted in the U.S (Figure 1). Several other studies have reported no increase of risk for workplace exposures without providing specific data (*).

A second exposure category in epidemiologic studies addresses people exposed to ETS at home since childhood, and the combined assessment from these studies shows no overall increase of lung cancer risk (Figure 2). This result comes despite general claims by EPA and other agencies that children are an especially susceptible lot. Adopting an unjustifiable selectivity, the EPA decided not to consider data from these and the negative workplace studies in its risk assessment exercise.

(*) MOSHAB should also be aware of certain inconsistent published reviews of workplace studies that have not specifically addressed ETS exposures. For instance, a recent review by Siegel reports that " (s)moking rates in cooks are 30% higher than in the general male population"(10). The same reviewer also reports that, after controlling for active smoking, cooks as a group do not show an increased risk of lung cancer, suggesting that ETS is not a risk factor. With the possible exception of nicotine, known ETS components are also found in much higher concentrations in the smokes, fumes, and gases to which cooks are occupationally and continuously exposed. Siegel then proceeds to make the implausible – and in fact contradictory – inference that ETS might be responsible for the slight increase of lung cancer risk reported for restaurant workers in general, a group that by his own admission should be exposed to less ETS and known environmental hazards than cooks themselves. Obviously, if the slight increase of risk for restaurant workers is real, it may be due to factors other than ETS.

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A third category of exposure in epidemiologic studies involves some 30 studies from all over the world, which address nonsmoking wives reportedly exposed to the ETS generated by their smoking husbands at home. Of these studies, some reported a small increase in risk, some no risk change at all, and some actually reported a decrease of risk (Figure 3). The EPA based its risk assessment on 11 US spousal exposure studies, none of which reports an overall statistically significant increase of risk at the 95% confidence level. The results of these studies are compatible with either an increase or a decrease of risk (1).

I would like to make clear that this not just my opinion about epidemiologic data. It is also the conclusion reached by the International Agency for Research on Cancer – an agency of the World Health Organization – which stated in 1986:

"... [S]ubstantial difficulties in [the] determination of passive exposure to tobacco smoke and to other possible risk factors [exist]. The resulting errors could arguably have artificially depressed or raised estimated risks, and, as a consequence, each is compatible either with an increase or with an absence of risk." (11)

EPA's further arbitrary decision was to ignore the two latest completed studies on ETS, funded by the National Cancer Institute and reporting data that do not agree with the Agency's conclusions (12,13).

The inconsistency of epidemiologic studies derives from the many problems they share. It is difficult if not impossible to define with any credibility the lifetime exposure to ETS of any person, especially deceased ones. More important, studies show that on the average 4% to 5% of self reported nonsmokers misrepresent their status and are in fact smokers. That proportion may be considerably greater when the subjects interviewed are lung cancer patients, as in the case of ETS studies (14,15). To reach its preconceived

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conclusions, EPA used an arbitrarily low misclassification adjustment, when a realistic one – even one below average reported rates -- would have voided any reports of increased risk (1,14).

There is more. Despite much epidemiologic evidence to the contrary, EPA largely discounted manifest confounders of lung cancer risk, such as differences in nutrition, disease experiences, physical activity, socioeconomic status, occupation, and others. The scientific literature reports over two dozen independent risk factors for lung cancer, and these confounders are more than capable of accounting for the small risk attributed to ETS by the Agency (8,14). One cannot look at ETS alone, as the agency has apparently done. It is as if police came upon a case involving several people, but arrested only one because he "looked" suspicious.

Also, EPA subverted accepted statistical standards, and doubled from 5% to 10% the margin of error it usually accepts in determining statistical significance (1). The arbitrariness of this gambit is apparent, considering that the Agency would refuse to consider regulatory petitions based on less than the 5% standard.

It should be made clear that the Agency did not conduct studies of its own: it simply reviewed studies performed by others. Despite results compatible with increased or decreased risk, the Agency arbitrarily decided to consider only increased risk. Indeed, the EPA report states that its conclusions were "...based on the a priori hypothesis...that a positive association exists between exposure to ETS and lung cancer."(1, page 5-2). Actually, the Agency's prejudice against ETS was made public in official documents as early as 1989 (16).

Thus, EPA's claim that ETS causes 3060 lung cancers a year is based on unwarranted assumptions, selective use of data, artful procedural manipulations, and the contrived illusion of mathematical precision (1). The EPA Science Advisory Board itself advised

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the Agency against producing numerical estimates (17). Dr. Erich Bretthauer, then Associate Administrator for R&D at EPA had to admit in official correspondence that the excess risk of lung cancer could also be virtually zero (18). In fact, there was dissent within EPA itself, and prominent internal EPA reviewers documented their criticism of the Agency's report (19)

EPIDEMIOLOGIC STUDIES DO NOT SUGGEST THAT ETS IS A CARDIOVASCULAR RISK FACTOR IN THE WORKPLACE.

The EPA report could not find reason to address ETS exposure as a possible cardiovascular risk. Other reviewers, however, have contrived to make such claims. Steenland, the most quoted of these reviewers, estimated at 1.3 the average excess risk from a pool of nine epidemiologic studies of cardiovascular diseases and ETS (20). Several individual studies, however, give reduced risk reports (14,20).

To understand the meaning of these pooled values, it is important to recall that the apparent risk of cardiovascular diseases for active smokers is only 1.7. And even for active smokers there are solid reports of negative cardiovascular risks in the Framingham female sample (21), among British doctors (22), and in a large Swedish study (23).

Steenland sensed the paradox and rushed to assert that "arguments inferring ETS health effects based on known health effects of mainstream smoke...are not appropriate", in contradiction to official EPA assertions (20). Indeed, such inference would be disturbing because the apparent reported risk in active smokers is only slightly higher than the

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reported risk from ETS studies, despite vastly smaller ETS doses. The closeness of the reported risk values indicates either the unlikely hypothesis of extreme differences in the specific biologic potencies of ETS and main-stream smoke, or the more plausible likelihood of interferences from confounding risk factors other than ETS. Steenland writes:

"Due to the relatively slight increased risk of heart disease for passive smokers and the many factors known to affect heart disease, the possibility of uncontrolled confounding as a cause for the increased risk cannot be ruled out." (20).

In fact, the role of confounders is certain, given that over 250 risk factors are reported in the literature and only a few of the nine studies of ETS and cardiovascular diseases have controlled at most for two or three of these factors (8,20). Nonetheless, setting aside all troubling considerations raised in his own paper, Steenland calculates ischemic heart disease deaths attributed to ETS with digital accuracy ranging from 74 to 18,390 units (20). Without explanation or supporting data, he assumes that the epidemiologic evidence is "reasonably accurate," that misclassifications and confounders are not "likely accounts for the observed risks," and that epidemiologic data are valid because "multiple studies are now consistent and reasonably well designed."

Objectively, these assumptions and conclusions are incompatible with the data. The consistency of some -- not all – available studies more likely reflects consistent simplistic designs, consistent disregard of confounders, and consistent likelihood of bias. In fact, the objections reviewed above in regard to lung cancer studies are equally valid objections to the execution and interpretation of epidemiologic studies of ETS and cardiovascular risk.

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THE SURGEON GENERAL AND OTHERS REPORT NO STATISTICALLY SIGNIFICANT ASSOCIATION OF ETS AND RESPIRATORY DISEASES IN ADULTS

No clear association of ETS and respiratory diseases in adults has been established, despite many studies. The US Surgeon General Report on ETS (5) stated:

".. a previously healthy individual would not develop chronic lung disease solely on the basis of [ETS exposure in adult life]". Regarding airflow obstruction, the same report noted "quite small" change in test subjects, and stated: "..it is unlikely that this change in airflow, per se, results in symptoms."

Parallel conclusions were drawn by the National Academy of Sciences (6). Subsequent studies confirmed the situation even for highly susceptible individuals, prompting the following assessment by Samet, a prominent ETS opponent:

"Neither epidemiological nor experimental studies have established the role of ETS in exacerbating asthma in adults..... Other studies have not shown chronic effects of involuntary exposure to tobacco smoke in adult nonsmokers."(24).

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EPA'S REPORT ON ETS IS NOT SCIENTIFICALLY JUSTIFIED. IT IS AN EXPEDIENT POLITICAL GAMBIT IN A LONG EPA TRADITION OF BENDING SCIENCE TO SUIT POLICY AIMS.

I wish to make it clear that my comments should not be interpreted to imply that ETS entails no risk at all. The essence of my critique is that the epidemiologic data are too uncertain to draw any conclusion that is scientifically justified. This critique applies to individual studies, as well as to other published reviews, such as the one by Steenland claiming an association of ETS and cardiovascular diseases (20), and the one by Siegel, claiming an increased risk for restaurant workers (10).

EPA claims to have used a "weight of evidence" approach. However, the agent in question -- ETS -- has been characterized only indirectly by a proxy that EPA itself later discounts. Many other agents should be considered with even greater reason, but were summarily ignored or dismissed. There are irrefutable alibis of misclassification, and no conclusive proof. By its own admission, EPA made a very selective use of the available studies, emphasizing only those that support its preconceived objectives.

Despite these fatal shortcomings as an objective scientific document -- and although EPA asserts to have no regulatory aims -- the Agency's ETS report has been invoked uncritically at face value by all levels of federal and local governments in support of strict regulations to eliminate ETS in public and work places. Many have attempted to describe ETS as a major issue in indoor air quality, and a prime factor in what has come to be known as the "sick building syndrome".

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In reality, published data show that in normal situations nonsmoker reactions to ETS depend more on psychosomatic and culturally determined aversions than on actual irritation (25,26). The National Institute for Occupational Safety and Health estimated that less than 2% of sick building complaints might have had an ETS component (27). Other sources of indoor air deterioration are overwhelmingly more prevalent and important than ETS (27,28).

Such liberties with policy and scientific manipulations are part of a pattern of behavior at EPA. In 1991, an independent blue ribbon panel was convened by William Reilly, the former EPA Administrator, to investigate accusations of "junk science" at the Agency. The panel concluded that the Agency does not have a coherent science agenda and suffers from poor scientific credibility because it has not secured adequate external support from the scientific community at large. More to the point, the panel concluded that EPA's science often seems to have been adjusted to endorse policy, an especially relevant statement when considering the Agency's report on ETS (29).

A regulatory agency does not fulfill the public expectations of due process and fairness, if it operates on the basis of unwarranted assumptions. At the very least, it should obey generally accepted norms of scientific evidence and conduct: norms that are independently justified by their transparent and rational honesty and timeless ethical value.

In the case of ETS, objective scientific data do not support a workplace smoking ban, nor do they show that – if enacted – such a ban would impart any demonstrable benefit to workers.

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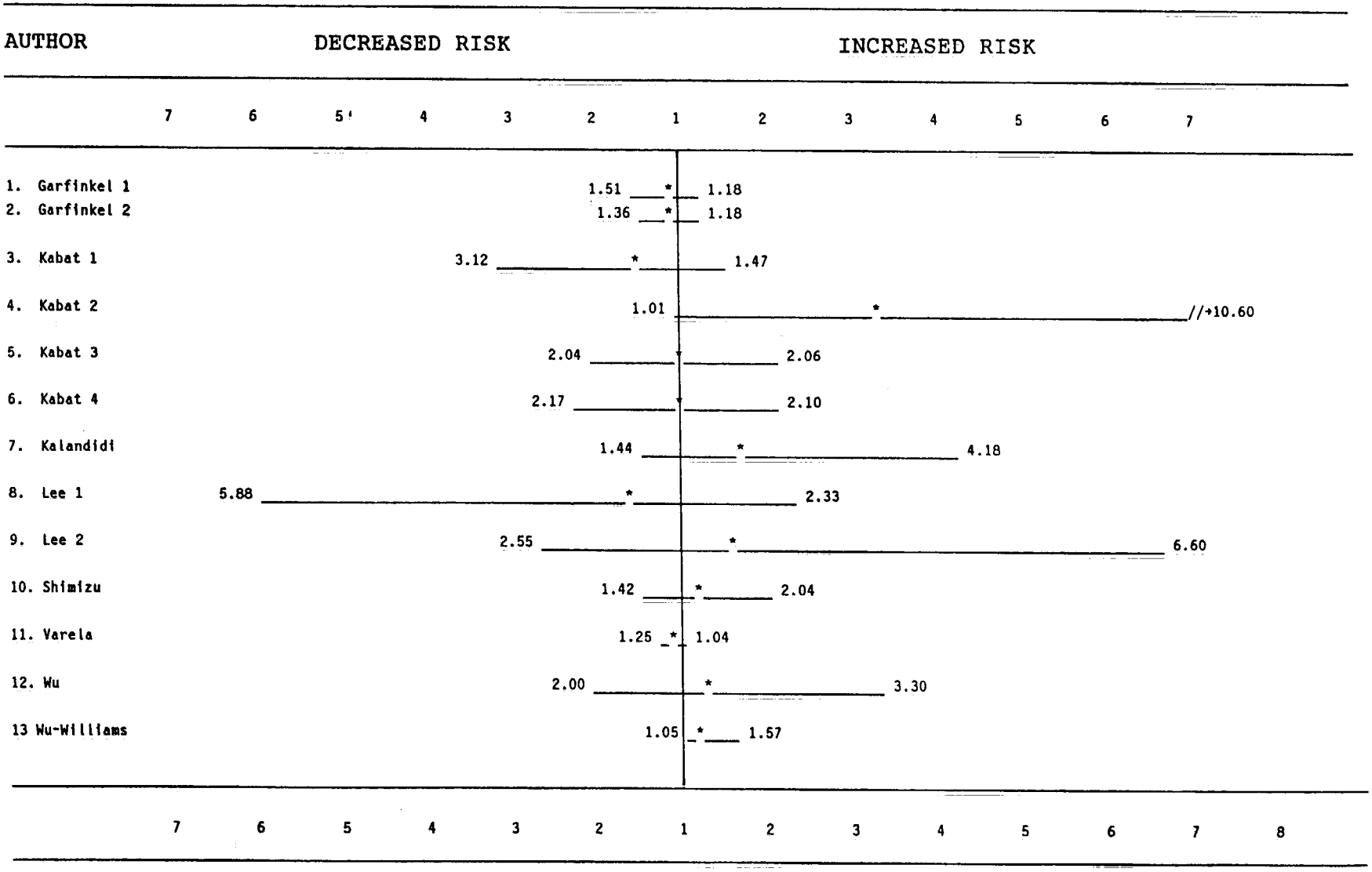
FIGURE 1 *

SYMMETRIC SCALE DISPLAY OF INCREASED AND DECREASED LUNG CANCER RISK
IN NEVER SMOKERS EXPOSED TO ENVIRONMENTAL TOBACCO SMOKE AT WORK



References: 1,14.

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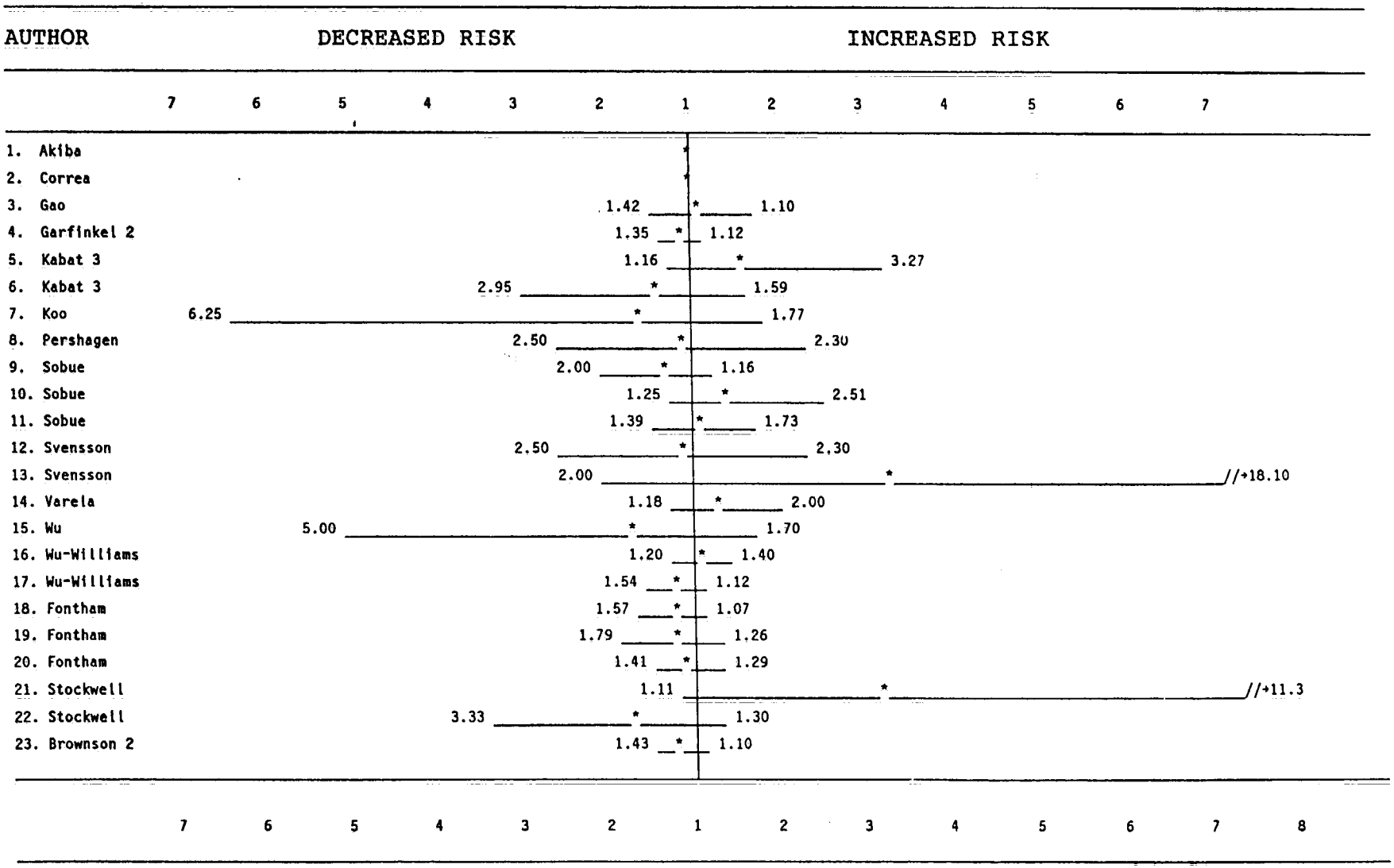
FIGURE 2 *

INCREASED AND DECREASED RISK OF LUNG CANCER

IN NEVER SMOKERS EXPOSED TO ENVIRONMENTAL TOBACCO SMOKE DURING CHILDHOOD



References: 1,12,13,14

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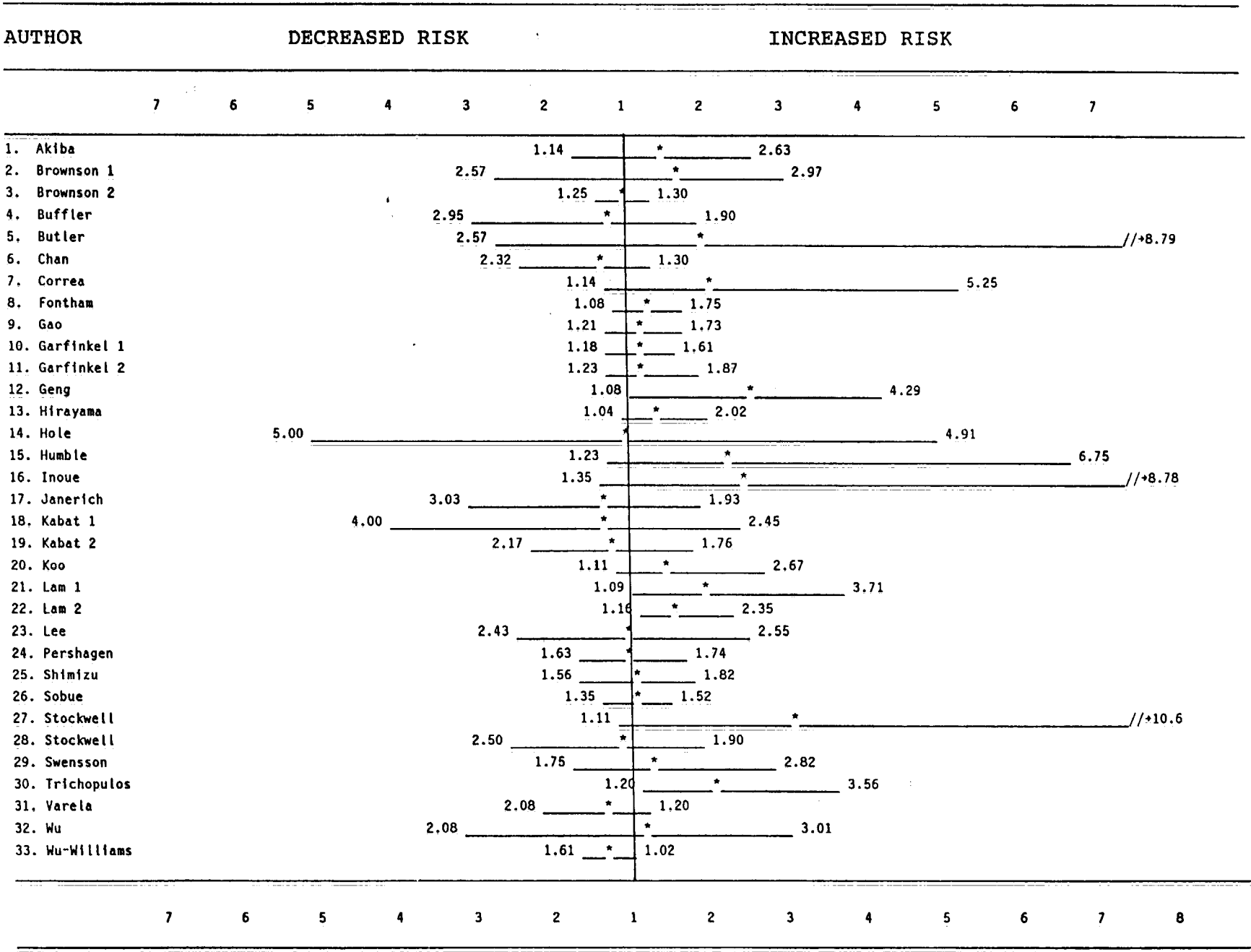
FIGURE 3 *

INCREASED AND DECREASED LUNG CANCER RISK IN NEVER SMOKING FEMALES MARRIED TO SMOKERS



References: 1, 12, 13, 14

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DR. GIO BATTA GORI

Director, Health Policy Center. Heads a program of studies for an independent assessment of health hazards and risks, of costs and benefits of regulation, and the formulation of policy alternatives compatible with health and safety, and with a sound economy. Consultant to major United States and European organizations in toxicology, epidemiology, nutrition and related product development and regulatory issues .

PROFESSIONAL PROFILE

Broad experience in toxicology, epidemiology, carcinogenesis, and with industrial R&D planning, management and decision making. Exerted national leadership in carcinogenesis research, methods and priorities of carcinogen testing, epidemiology, smoking and health, nutrition, ozone depletion and ultraviolet radiation, cost and benefit analysis of prevention policies, safety and carcinogen regulation. Played key roles in the successful passage of the 1970 Cancer Act and subsequent appropriations. Planned and managed research and intervention programs of national and international scope, establishing consensus priorities in cancer causation, prevention and control, and patient management. First hand understanding of federal research and regulatory agencies, the budgetary and appropriations process, Congress and legislative operations, the diversity of motivation in private enterprise, academia, advocacy groups, and a pluralistic socioeconomic reality. Direct multilingual contacts with parallel issues and organizations in Europe. Numerous appearances at congressional hearings. Congressional contacts and familiarity with the lay and scientific media. Extensive experience in industrial and management consulting.

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EDUCATION

Doctor of Biological Sciences, University of Camerino (Italy), 1956. Financial Analysis Program, Dun and Bradstreet School of Business, 1965. Program for Senior Managers in Government, Harvard Business School, 1977. Master of Public Health, Johns Hopkins University, 1979.

POSITIONS HELD

From 1980 to 1987, Dr. Gori was Director of The Franklin Institute Policy Analysis Center. Before, he held several positions at the National Cancer Institute (1968-1980), most recently as Deputy Director of the Division of Cancer Cause and Prevention (1972-80), with simultaneous responsibilities as Acting Associate Director, Carcinogenesis Program (1976-1978); Director, Diet, Nutrition and Cancer Program (1973-1980); Associate Scientific Director for Program, DCCP (1968-1972); Director, Smoking and Health Program (1968-1980).

Was previously Director of the Biological Research Laboratory at Litton Systems, Inc., Bethesda, Maryland, (1967-1968); Head of the Virology, Immunology, and Toxicology Sections at Melpar, Inc., Falls Church, Virginia, (1965-1967); Assistant to the President for Technical Affairs, Director of Quality Control, and Director of Production at Microbiological Associates, Inc., Bethesda, Maryland, (1962-1965).

Earlier research positions were Associate, Wistar Institute, Philadelphia, Pennsylvania; Associate Director, Istituto Sclavo, Siena, Italy; Research Associate, Virus Research Laboratory, University of Pittsburgh, Pennsylvania; and Associate, Microbiology and Virus Department, Istituto Superiore di Sanita', Rome, Italy.

EDITORIAL ACTIVITIES

Nutrition and Cancer, An International Journal - Editor
Journal of Toxicology and Environmental Health - Editorial Board
Regulatory Toxicology and Pharmacology - Editorial Board

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PROFESSIONAL AFFILIATIONS

Diplomate: The Academy of Toxicological Sciences
Society of Toxicology: former member, Technical Committee, Regulatory Affairs and Legislative Assistance Committee
Toxicology Forum
American Society for Parenteral and Enteral Nutrition
American Public Health Association
American Association for the Advancement of Science
International Society of Regulatory Toxicology and Pharmacology : President.
National Institutes of Health Alumni Association: Board Member.

ADDRESSES

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AWARDS

Public Health Service Superior Service Award - 1976

"For contributions to broad-ranging programs in cancer causations in both national and international operations and leadership and management of the Smoking and Health Program."

HONORS

Chairman

Conference, New Techniques in Virus Production, Annual Meeting, Society for Industrial Microbiology, Burlington, Vermont, August 1970.

Tobacco Working Group, NCI, 1970-1980.

Tobacco Segment, Carcinogenesis Area, NCI, 1970-1974.

Liaison Subcommittee, Joint Committee on Smoking and Health (HEW, AMA, CTR, HEW Secretary Sponsor), 1971-1973.

Study Group for Reverse Transcriptase Antagonists (NCI), 1971-1972.

Pharmocological and Clinical Approaches in Smoking Working Group, 1971-1973 (NCI).

Session on Smoking and Lung Cancer, Conference on Lung Carcinoma, National Cancer Institute, Bethesda, Maryland, March 1972.

Ultraviolet Radiation and Skin Cancer Committee (HEW-DOT), 1972-1974.

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Dietary Factors and Cancer of the Large Bowel, Conference on Nutrition in the Causation of Cancer, American Cancer Society and the National Cancer Institute, Key Biscayne, Florida, March 1975.

Human Health Effects Group, Biologic Assessment Program of Inadvertent Modification of the Stratosphere, Environmental Protection Agency, Washington, DC, 1976.

Conference on Nutrition and Cancer Therapy, American Cancer Society and the National Cancer Institute, Key Biscayne, Florida, November 1976.

Symposium on Bioassay Models and Inhalation Toxicology, Tampa, Florida, 1976.

Organizing Committee, National Conference on Nutrition and Cancer, American Cancer Society, Seattle, Washington, 1978.

Interagency Committee for Stratospheric Ozone Protection - EPA - Health Effects Group, 1979.

Program Committee, International Society of Regulatory Pharmacology and Toxicology, 1986-.

Environmental Tobacco Smoke Session. The Toxicology Forum, February 1990, Washington, DC.

Environmental Tobacco Smoke Session. The Toxicology Forum. July 1990, Budapest.

Epidemiology Session. Symposium on chemical carcinogenesis: The relevance of mechanistic understanding in toxicological evaluation. Bundesgesundheitsamt. Berlin, Germany, April 29-30, 1991.

Executive Secretary

Tobacco Working Group, 1969-1980.

Cancer Cause and Prevention Advisory Committee, NCI, 1970-1978.

Smoking and Health Committee, National Cancer Advisory Board, 1973- 1978.

Diet, Nutrition and Cancer Program Advisory Committee, NCI, 1975-1978.

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Cancer and Nutrition Scientific Review Committee, NCI, 1976-1978.

Carcinogenesis Scientific Advisory Committee, NCI, 1976-1978.

Member

Committee for the Definition of Hazardous Substances in Tobacco Smoke, National Clearinghouse for Smoking and Health, Rockville, Maryland, 1970.

Advisory Group for Pesticide Residues in Tobacco, USDA, Washington, DC, 1971.

Organizing Committee, XI International Cancer Congress, 1971-1974.

Committee on Tobacco and Cancer, American Cancer Society, 1971-1978.

IARC/WHO Committee on Evaluation of Carcinogenic Risks of Chemicals to Man, 1972-1978.

Organizing Committee, III International Conference on Smoking and Health, 1973-1975.

Workshop on Approaches to Assess the Significance of Experimental Chemical Carcinogenesis Data for Man, Brussels, Belgium, 1973.

Molecular Control Working Group, NCI, 1973-1976.

Review Task Force, ARS-USDA Activities in Tobacco Research, 1973-1980.

Kentucky Tobacco and Health Research Board, Louisville, Kentucky, 1975-1978.

Nutrition Coordinating Committee, NIH, 1975.

Task Force on Tobacco and Cancer, American Cancer Society, 1975-1976.

Committee on Prevention, Institute of Medicine, 1975-1979.

Board of Scientific Advisors, American Society for Enteral and Parenteral Nutrition, 1977-1979.

Organizing Committee, NIH Conference on Nutrition, 1978.

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International Union of Nutritional Sciences. Workshop, Committee on Nutrition and Cancer, Cambridge, England, 1980.

Task Force on the Delaney Clause, Council for Agricultural Science and Technology, Washington, DC, 1980.

Technical Committee, Society of Toxicology, 1980-1981.

American Council on Science and Health, Steering Committee, 1981.

Legislative Committee, Society of Toxicology, 1982-1983.

Regulatory Affairs and Legislative Assistance Committee, Society of Toxicology, 1983-1984.

Scientific Committee of the 3rd Annual Symposium of the European Organization of Cooperation in Cancer Prevention Studies, 1983-1985.

Council Board . International Society for Regulatory toxicology and Pharmacology. 1985-.

Invited Speaker, selected meetings

Planning and Management of Research, Carlo Erba Foundation and National Tumor Institute, Milan and Rome, 1970.

Continuous Cultivation of Viruses, Istituto Superiore di Sanita, Rome, 1970.

Continuous Cultivation of Viruses, Society for Industrial Microbiology, Annual Meeting, Burlington, Vermont, 1970.

Research for a Less Hazardous Cigarette, Second International Smoking and Health Conference, London, England, 1971.

Planning and Management of Scientific Research Programs, Grants Associates Seminars, National Institutes of Health, Bethesda, Maryland, 1971.

Smoking and Lung Cancer, Conference on Carcinoma of the Lung, National Cancer Institute, Bethesda, Maryland, 1972.

Ranking of Suspicion of Hazard of Environmental Contaminants, Advisory Committee, Toxicology Information Program, National Library of Medicine, Bethesda, Maryland, 1972.

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Ranking of Environmental Contaminants for Bioassay Priority, Second International Symposium on Cancer Detection Prevention, Bologna, Italy, 1973.

Search for Less Hazardous Cigarette, XI International Cancer Congress, Florence, Italy, 1974.

Prevention of Smoking Related Disease -Seminar- Roswell Park Memorial Institute, Buffalo, New York, 1974.

Smoking Cessation Clinics, National Cancer Institute of Brazil, Rio de Janeiro, Brazil, 1975.

Tobacco Particulate Matter, Third World Conference on Smoking and Health, New York, New York, 1975.

Ranking of Environmental Contaminants for Bioassay Priority, Workshop on the Investigation of the Carcinogenic Burden by Air Pollution in Man, Hannover, Germany, 1975.

A Program for Control of Smoking Related Diseases-- A Consulting Seminar --The Government of the Philippines, Manila, 1975.

Nutrition and Cancer, XI International Congress on Nutrition, Kyoto, Japan, 1975.

Dietary Factors and Cancer of the Large Bowel Conference on Nutrition in the Causation of Cancer, American Cancer Society and the National Cancer Institute, Key Biscayne, Florida, 1975.

Less Hazardous Cigarettes, 3rd International Symposium on Detection and Prevention of Cancer, New York, New York, 1976.

Diet, Nutrition and Cancer Program, Candlelighters Meeting, Washington, DC, 1976.

Colloquium on Nutrition and Cancer, Oak Ridge National Laboratories, 1976.

Nutrition and Cancer -Seminar- Fred Hutchinson Cancer Center, Seattle, Washington, 1976.

Diet, Nutrition and Cancer, Food Research Institute, Madison, Wisconsin, 1976.

Nutrition as a Possible Cause of Cancer, Massachusetts Dietetic Association, Framingham, Massachusetts, 1976.

Cancer and Diet, American Dietetic Association, Boston, Massachusetts, 1976.

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UICC Workshop on Lung Cancer, Geneva, Switzerland, 1976.

Food and Nutrition Liaison Committee Meeting, Naples, Florida, 1976.

Nutrition and Cancer Symposium, Columbia University, New York, New York, 1976.

Nutrition and Cancer Therapy, American Cancer Society, New York, 1976.

Prevention of Smoking Related Diseases, Institute of Medicine, National Academy of Sciences, 1977.

American Dietetic Association Legislative Workshop, Washington, DC, 1977.

Diet, Nutrition and Cancer, Brookhaven National Laboratory, Upton, New York, 1977.

Nutrition and Cancer, Foundation Curie, Paris, France, 1977.

Nutrition and Cancer, 18th Annual Meeting of the American College of Nutrition, Houston, Texas, 1977.

Nutritional Variables in Perinatal Carcinogenesis, 6th Perugia Quadrennial International Conference on Cancer, Perugia, Italy, 1977.

Conference on Commonalities in Substance Abuse and Habitual Behavior, Airlie House, Warrenton, Virginia, 1977.

Conference on Ultraviolet Carcinogens, Airlie House, Warrenton, Virginia, 1977.

Reducing the Hazard and Addictive Properties of Cigarettes, Alcoholism and Drug Abuse Institute's Summer Conference, Seattle, Washington, 1977.

Nutrition and Cancer, International Conference on Cancer and Environment, Montreal, Canada, 1977.

Symposium on Smoking and Health, University of Munich, West Germany, 1977.

Symposium on Smoking and Health, UNAMSI, Milan, Italy, 1977.

Prevention Alternatives to Raising Disease Costs, American Health Foundation, New York, 1977.

Consulting Party on Less Hazardous Cigarettes, Canadian Government, Ottawa, January 1978.

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Advisory Symposium in Nutrition, Kellogg Foundation, Battle Creek, Michigan, April 1978.

Conference on Health Economics, Hudson Institute, Washington, DC, May 1978.

International Symposium on the Chemical Toxicology of Foods, Milan, Italy, 1978.

Drug Dependence Conference, Baltimore, 1978.

ACS-NCI Conference on Nutrition and Cancer, Seattle, Washington, August 1978.

Workshop on Carbon Monoxide Toxicology, Ministry of Health, Berlin, West Germany, 1978.

Governor's Conference on Nutrition, Minneapolis, Minnesota, November 1978.

Symposium on Environmental Determinants of Cancer, New York University, New York, January 1979.

Smoking and Health Program Conference, Savannah, Georgia, 1979.

Smoking and Health Conference, Celle, West Germany, April 1979.

Nutrition and Cancer, Meeting of the American Society of Clinical Oncology, New Orleans, May 1979.

Institute of Food Technologists Meeting, St. Louis, Missouri, June 1979.

Fourth International Symposium on the Prevention and Detection of Cancer, London, England, 1980.

Nutrient Intake and Carcinogenesis, Western Maryland Nutrition Symposium for Health Care Professionals, Frostburg State College, Maryland, November 1980.

Environment and Cancer, Maryland Cancer Program, Pathobiology and Management of Neoplastic Diseases course, University of Maryland, Baltimore, Maryland, November 1980.

James M. Perelman Visiting Professor in Oncology, Akron General Medical Center, Akron, Ohio, November 1980.

Visiting Lecturer, Kellogg National Fellows, Pontiac, Michigan, November 1980.

International Conference on the Environmental Aspects of Cancer, American Health Foundation, New York, New York, February 1982.

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Association of Food and Drug Officials/Association of Official Analytical Chemists Workshop, New Orleans, Louisiana, April 1982.

Annual Meeting of the American College of Neuropsychpharmacology, San Juan, Puerto Rico, December 1982.

Cancer hazards, risks and thresholds: an Assessment. Cancer and the Environment Symposium. International Center for Environmental Health Sciences. New York, 1983.

Cancer and Dietary Connections...If Any, 1983 Nutrition Press Symposium, Texas Cattle Feeders Association, Phoenix, Arizona, March 1983.

Dietary Factors and Carcinogenesis, Sixth World Congress of Food Science and Technology, Dublin, Ireland, September 1983.

Side-Stream Smoke: Fact and Fiction, Passive Smoking Workshop, American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc., Atlanta, Georgia, February 1984.

Panel Chairman: De minimis and drinking water standards. International Society for Regulatory Pharmacology and Toxicology. Annual Meeting. Washington, DC, 1987.

Epidemiology and the concept of causation in multifactorial diseases. International Society for Regulatory Pharmacology and Toxicology. Annual Meeting, Baltimore, 1988.

The holy grail: or the mechanisms of cancer causation. Symposium on chemical carcinogenesis: the relevance of mechanistic understanding in toxicological evaluation. Bundesgesundheitsamt, Berlin, Germany, April 29-30, 1991.

Epidemiology and quantitative cancer risk assessment. Workshop on " A review of Risk assessment and OMB's report on its application in regulatory agencies. Workshop organizer, discussion panel moderator, and rapporteur. International Society of Regulatory Toxicology and Pharmacology, Crystal City, Va. June 11, 1991.

Ups and downs of cancer incidence rates - Projections for the next century. Workshop organizer and final panel moderator. International Society of Regulatory Toxicology and Pharmacology. Crystal City, Va. October 16, 1991.

Nutritional effects in evaluating carcinogenicity data. Invited presentation. 12th Annual Meeting, American College of Toxicology, Savannah, Georgia, October 22, 1991.

New directions in risk assessment. Invited Presentation. American Industrial health Council. Annual Meeting, Washington DC, December 1, 1992.

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Numerous Television and Radio Interviews on the Subjects of Cancer Prevention, Smoking and Health and Nutrition and Cancer. 1970-1980.

Several Appearances at Congressional Hearings on Ultraviolet Radiation and Cancer, Smoking and Health and Nutrition. 1970-1980.

BIBLIOGRAPHY

Penso, G., V. Ortali and G.B. Gori: Contribution to the morphological and biochemical study on halophilic bacteria. Symposium on Brines, Cambridge, England, pp. 21-28, 1957.

Lelli, G., D. Balducci and G.B. Gori: Contribution to the morphological study of in vitro cultivated cells. (Italian). Rend. Istit. Sup. Sanita 20:1113-1125, 1957.

Gori, G.B.: Automatic trypsinization of animal tissues. (Italian). Rend. Istit. Sup. Sanita 21:850-865, 1958.

Frank, M. and G.B. Gori: Automatic control of continuous biological processes through medium turbidity. (Italian). La Ricerca Scientifica 28:2023-2030, 1959.

Felici, A., D. Balducci and G.B. Gori: Annual Proceedings of the Research Activities of the Virus Department (1957). (Italian). Rend. Istit. Sup. Sanita 22:345-355, 1959.

Gori, G.B.: Soil algae and their altitudinal distribution on the Sibillini Appennins. (Italian). Ph.D. Thesis, 1956. Rend. Istit. Sci. Univ. Camerino 1:113-125, 1960.

Felici, A., D. Balducci and G.B. Gori: Annual Proceedings of the Research Activities of the Virus Department (1958). (Italian). Rend. Istit. Sup. Sanita 23:503-514, 1960.

Salk, J.E. and G.B. Gori: Theoretical, experimental and practical considerations in the use of formaldehyde for the inactivation of poliovirus. Ann. NY Acad. Sci. 83:609-637, 1960.

Balducci, D., G. Andreoni and G.B. Gori: Cytopathic index: A new method for quantitative evaluation of tissue culture infectivity of different virus strains. J. Bacteriology 79:379-383, 1960.

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Gori, G.B.: The Lysostat: Apparatus for the dynamic investigation and growth of virus-carrying or sterile cell populations. Ann. Sclavo 2:529-533, 1960.

Gori, G.B.: Trypsinization of animal tissues for cell culture: theoretical considerations and automatic apparatus. Applied Microbiology 12:115-121, 1964.

Gori, G.B. and D.Y. Lee: A method for the eradication of Mycoplasma infections in cell cultures. Proc. Soc. Exptl. Biol. Med. 117:918-921, 1964.

Gori, G.B.: Chemostatic concentrated culture of heteroploid mammalian cell suspensions in dialyzing fermentors. I. Experimental evidence and theoretical considerations. Applied Microbiology 13:93-98, 1965.

Gori, G.B.: The Lysostat: Single and multistage continuous cultivation of viruses in cell suspensions. Theoretical and experimental evidence. Applied Microbiology 13:909-917, 1965.

Gori, G.B.: Medium pollution rates in cell cultures. J. Nat. Cancer Inst. 44:275-281, 1970.

Gori, G.B.: The continuous cultivation of viruses. In: Developments in Industrial Microbiology 11:20-31, 1970. American Institute of Biological Sciences, Washington, DC.

Gori, G.B.: Research in Smoking and Health at the National Cancer Institute. JNCI 48:1759-1762, 1972.

Gori, G.B.; Smoking and cancer: research in etiology and prevention at the National Cancer Institute. Cancer 30:1340-1343, 1972.

Tso, T.C. and G.B. Gori: Effect of tobacco characteristics on cigarette smoke composition. In: The Chemistry of Tobacco and Tobacco Smoke. New York, Plenum Publishing Corp., pp. 51-64, 1972.

Gargus, J.L., J.J. Gart, R.P. Kwapien and G.B. Gori: Replicate control values in large scale mouse dermal bioassays of tobacco smoke condensates. Toxicology and Applied Pharmacology 25:478, 1973.

Battista, S.P., M.R. Guerin, G.B. Gori and C.J. Kensler: A new system for quantitatively exposing laboratory animals by direct inhalation. Archives of Environmental Health 27:376-382, 1973.

Stoner, G.D., M.B. Shimkin, A.J. Kniazeff, J.H. Weisburger, E.K. Weisburger and G.B. Gori: Test for carcinogenicity of food additives and chemotherapeutic agents by the pulmonary tumor response in strain A mice. Cancer Research 33:3069-3085, 1973.

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Hoffmann, D., K.D. Brunnemann, G.B. Gori and E.L. Wynder: On the carcinogenicity of marijuana smoke. In V.C. Runeckles (ed.), Recent Advances in Phytochemistry, Vol. 9, Plenum Publishing Corp., New York, 1975.

Tso, T.C. and G.B. Gori: Leaf quality and usability - theoretical model I. In Chemical Marketing and Economics. American Chemical Society, Philadelphia, Pennsylvania, p. 258-275, 1975.

Tso, T.C. and G.B. Gori: Leaf quality and usability - theoretical model I. Beitr. Tabakforschl., Vol. 8, 1975.

Patel, A.R. and G.B. Gori: Preparation and monitoring of marijuana smoke condensate samples. Bull. Narc. 27:47, 1975.

Gori, G.B.: Artificial tobacco substitutes. J. Am. Med. Assoc. 234:489-490, 1975.

Gori, G.B. and J.A. Peters: Etiology and prevention of cancer. Prev. Med. 4:239-246, 1975.

Gori, G.B.: Summary of the informal discussion of dietary factors and cancer of the large bowel. Cancer Res. 35:3432-3436, 1975.

Gori, G.B.: The diet, nutrition, and cancer program of the NCI National Cancer Program. Cancer Res. 35:3545-3547, 1975.

Gori, G.B. (Ed.): Proceedings of the Tobacco Smoke Inhalation Workshop on Experimental Methods in Smoking and Health Research. DHEW Publication No. NIH-75-906, 84 pp. 1975.

Hoffman, D., C. Patriankos, K.D. Brunnemann and G.B. Gori: Chromatographic determination of vinyl chloride in tobacco smoke. Anal. Chem. 48:47-50, 1976.

Gori, G.B.: Approaches to the reduction of total particulate matter (TPM) in cigarette smoke. In: Proceedings/3rd World Conference on Smoking and Health - Modifying the Risk for the Smoker. DHEW Publication No. (NIH) 76-1221, 1:451-461, 1976.

Brunnemann, K.D., D. Hoffmann, E.L. Wynder and G.B. Gori: The determination of tar, nicotine and carbon monoxide in cigarette smoke: a comparison of international smoking conditions. In: Proceedings. 3rd World Conference on Smoking and Health - Modifying the Risk for the Smoker. DHEW Publication No. (NIH) 76-1221, 1:441-449, 1976.

Tso, T.C., G.B. Gori and D. Hoffmann: Reduction of nicotine and tar in tobacco and cigarettes through agricultural techniques. In: Proceedings/3rd World Conference on Smoking and Health - Modifying the Risk for the Smoker. DHEW Publication No. (NIH) 76-1221, 1:35-48, 1976.

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Gori, G.B., S.P. Battista, P.S. Thayer, M.R. Guerin and C.J. Lynch: Chemistry and In Vitro Bioassay of Smoke from Experimental Filter Cigarettes. DHEW Publication No. (NIH) 76-1076, 42 pp.

Gori, G.B. (Ed.): Report No. 1 - Toward Less Hazardous Cigarettes - The First Set of Experimental Cigarettes. DHEW Publication No. (NIH) 76-905. 1976.

Gori, G.B. (Ed.): Report No. 2 - Toward Less Hazardous Cigarettes - The Second Set of Experimental Cigarettes. DHEW Publication No. (NIH) 76-1111. 1976.

Gori, G.B.: Low risk cigarettes: a prescription. Science 194:1243-1246, 1976.

Scotto, J., T.R. Fears and G.B. Gori: Measurement of Ultraviolet Radiation in the United States and Comparison with Skin Cancer Data. DHEW Publication No. (NIH) 76-1029, 1976.

Wynder, E.L, Hoffman, D., Gori, G.B., (Eds.), Proceedings of the Third World Conference on Smoking and Health: National Cancer Institute. DHEW Publication No. (NIH)76-1221. 1976.

Gori, G.B.: Contributor in: Lung Cancer - U.I.C.C. Technical Report Series No. 25, Wynder and Hecht Eds., Geneva, Switzerland, 1977.

Wynder, E.L. and G.B. Gori: Contribution of the environment to cancer incidence: an epidemiologic exercise. Journal of the National Cancer Institute 58:825-832, 1977.

Tso, T.C. and G.B. Gori: A novel approach in tobacco production as food source and smoke material - year 1976 to year 2000. Proc. VI Intern. Tobacco Sci. Congress, Tokyo, Japan, pp. 81-86, November 1976.

Gori, G.B. (Ed.): Report No. 3 - Toward Less Hazardous Cigarettes - The Third Set of Experimental Cigarettes. Number (BIH) 77-120. GPO, Washington, DC, 1977.

Gori, G.B.: Nutrition and cancer therapy. Cancer Research 37:2469-2471, 1977.

Gori, G.B.: Ranking of environmental contaminants for bioassay priority. In Air Pollution and Cancer in Man. World Health Organization. International Agency for Research on Cancer. Publication 16, Lyon, France, pp. 99-111, 1977.

Gori, G.B.: Diet and cancer. Journal of American Dietetic Association 17:375-379, 1977.

Gori, G.B. and B.J. Richter: The macroeconomics of disease prevention in the United States. Science 200:1124-1130, 1978.

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Gori, G.B. and C.J. Lynch: Toward less hazardous cigarettes. JAMA 240:1255-1259, 1978.

Gori, G.B.: Role of diet and nutrition in cancer cause, prevention and treatment. Bull. Cancer 65:115-126, 1978.

Gori, G.B.: Diet and nutrition in cancer causation. In Chemical Toxicology of Food, C.L. Galli, R. Paoletti, and G. Vettorazzi, Eds. Elsevier/North-Holland Biomedical Press, 1978.

Gori, G.B.: Diet and nutrition in cancer causation. Nutrition and Cancer 1:507, 1978.

Bock, F.G., Gori, G.B., Sebaceous gland suppression testt as an indicator of the carcinogenic activity of eperimental cigarette smoke condensate. Proceedings of the Sixth Annual Meeting of the Americal Association for Cancer Research. 19:43, March 1978.

Gori, G.B. and R.L. Ellis: Reduction of carbon monoxide in cigarette smoke. Prev. Med. 8:358-363, 1979.

Gori, G.B.: Summary of the workshop in carbon monoxide and cardiovascular diseases. Prev. Med. 8:404-408, 1979.

Gori, G.B.: Dietary implications in the multifactorial etiology of certain human cancers. Cancer 43:2151, 1979.

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Gori, G.B. and C.J. Lynch: Socially tolerable smoke, (Letter), JAMA 241:2142, 1979.

Gori, G.B. and C.J. Lynch: Toward less hazardous cigarettes, (Letter). JAMA 241:2143, 1979.

Gori, G.B.: Food as a factor in the etiology of certain human cancers. Food Technology 33:48-56, 1979.

Gori, G.B.: The regulation of carcinogenic hazards. Science 208:256-261, 1980.

Gori, G.B., (Ed.) Report No.4. Toward less hazardous cigarettes. The fourth set of experimental cigarettes. National Cancer Institute, Bethesda, Md. March 1980.

Gori, G.B.: Observed no-effect thresholds and the definition of less hazardous cigarettes. J. of Environmental Pathology and Toxicology 3:193-203, 1980.

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Good Morning!

I'm Steve Parrish, Senior Vice President and General Counsel of Philip Morris, USA.

At the outset, I would like to emphasize we are committed to working in a constructive and cooperative manner with the State of Maryland in this proceeding. We believe that if you are presented with relevant data, if you have the opportunity to view the data completely and fairly, and if you take the opportunity to observe the various working environments to which your regulatory decisions will apply, you will be in the best possible position to make a decision which protects worker health and safety without placing unwarranted

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burdens upon Maryland business and without unnecessarily intruding on the rights of individual workers.

Others will address in greater detail the legal and scientific issues raised by this proposed standard. I would like to comment on our Company's positions on issues that you are facing, including indoor smoking and the relationship of the EPA's risk assessment on ETS to indoor smoking.

Philip Morris Companies Inc. is the largest consumer packaged goods company in the world, with major tobacco, food and beer operations including Kraft, Miller Brewing, General Foods and Suchard. The Company's operating subsidiaries produce brand name products such as *Maxwell House, Sanka, Jell-O, Kool-Aid, Marlboro, Kraft cheeses, Oscar Mayer, Cool*

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Whip, and Miller Beer. The Company's interests in this matter are (1) as an employer, (2) as the owner and/or manager of buildings, and (3) as a manufacturer of cigarettes in the United States.

We recognize the complexity of the issues relating to a comprehensive consideration of indoor air quality. We also recognize the concerns of some individuals and organizations regarding the issue of environmental tobacco smoke. We acknowledge that some people may find smoking objectionable in the workplace, public buildings or government buildings. However, the rights of all individuals should be recognized and addressed, and local accommodation of both smokers and nonsmokers through reasonable measures tailored to the specific circumstances, can and should be encouraged.

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We believe that employers and building owners should address indoor smoking simply as one part or component of an overall building systems approach to total indoor environmental quality.

Many here today may argue against any approach to indoor smoking that does not result in a complete ban -- arguing that the EPA's risk assessment on ETS establishes that nonsmoker exposure to ETS causes cancer and other diseases. However, in our view, the EPA's risk assessment -- which does not focus on workplace data -- is among the most flawed ever issued by the Agency.

On January 7, 1993, the U.S. Environmental Protection Agency issued its final Risk Assessment on

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Environmental Tobacco Smoke, declaring it a Group A carcinogen. Since that time, there has been a flood of valid criticism of EPA's action, and those criticisms are reflected in subsequent litigation against the EPA.

The Council for Burley Tobacco, the Flue-Cured Tobacco Cooperative Stabilization Corporation, Gallins Vending Company, Universal Leaf, R.J. Reynolds and Philip Morris filed suit in U.S. District Court for the Middle District of North Carolina to have that EPA report declared null and void.

In essence, the lawsuit against the EPA levels three basic charges: First, EPA's preparation and publication of the ETS Risk Assessment violated the terms and limitations of

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EPA's limited authority under the Radon Act. In other words, EPA exceeded its statutory authority.

Second, EPA failed to follow its own publicly announced guidelines for conducting cancer risk assessments. Very simply, when the guidelines would not allow the EPA's predetermined conclusions, they were ignored.

Third, we believe that throughout the EPA risk assessment, the agency made numerous mistakes, and those mistakes were compounded by a series of data manipulations that violate established principles of science, as well as what should be principles of government.

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Further highlighting EPA's shortcomings, the National Cancer Institute this month published research indicating that poor diet alone is a risk factor for lung cancer in nonsmokers. Not one single study of ETS adequately adjusted for possible dietary effects. Neither did the EPA. The risks reported in the NCI diet study are sufficient to account for the risks attributed to ETS in the EPA's review of spousal smoking studies.

In science, confounding factors are not just minor matters. They are risk factors for the disease that must be addressed before any causal inference can be made. Not a single study reviewed by the EPA adequately accounted for the most important potential confounders -- particularly diet, genetic predisposition and occupational exposures.

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The EPA claims that ETS exposure is responsible for 3,000 lung cancer deaths annually among nonsmokers in the U.S. That figure was projected at by combining the risk estimates from 11 U.S. studies based on spousal smoking in the home and lung cancer in nonsmoking females. But the EPA encountered numerous problems with the data.

First, not one of the 11 individual studies reported an overall statistically significant risk for spousal smoking. So EPA tried to aggregate the results from all the studies and actually lowered the standard for statistical evaluation -- accepted by the scientific community and by EPA itself -- in order to force its conclusions.

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We and others pointed out to the EPA that it had failed to include the data from two U.S. studies published two months prior to the Risk Assessment's finalization.

To me personally, this is the single most egregious abuse of the scientific data by the EPA. They ran out of time, they said. There has to be a cut-off point, they said. However, while there was no time to incorporate the data from two major U.S. studies, there was time the EPA to include a study that isn't even finished, and when finished, will be unlikely to represent the conclusions that EPA drew from preliminary data.

But EPA and many others in the scientific community know exactly what those two U.S. studies would do if

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incorporated: negate the EPA findings. They will do that even with the lowered statistical standard.

There's more. EPA took its estimate of 1.19 based on spousal smoking in the home and extended it to all nonsmokers in all venues, including the workplace. Another problem: Fourteen of the studies considered by the EPA looked at nonsmoker exposure to ETS in the workplace. When the results from those studies are aggregated in EPA fashion, the risk estimate indicated, there's no increase in risk. EPA's reply? The database for the workplace is smaller that than for spousal smoking and workplace exposures are variable. (How the EPA would know the latter is curious because it did not consider the data from the major available studies on actual ETS exposures

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in the workplace.) EPA does not mention that the workplace data , if examined, contradict and negate its basic claims.

[So what does EPA's estimate of 3000 deaths really mean? The estimate, with all its splendor and pseudo-scientific wrappings, is spurious and not based on the actual data on ETS. The actual data are at least consistent with no discernible increased risk among nonsmokers.]

Thus, EPA manipulated and "cherry-picked" scientific data, ignored recent studies that contradicted its conclusions, and used scientific assumptions and methodologies not generally accepted by the scientific community or even by the agency itself in other risk assessments it had conducted in the past.

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When existing data failed to provide the agency with a sound scientific basis to declare ETS a known human carcinogen, it continued to select and manipulate the data until a statistical relationship between ETS exposure and lung cancer could be claimed. To force the result it wanted, EPA, in the midst of the risk assessment process, changed the statistical confidence interval from 95 percent to 90 percent in its analyses of U.S. studies.

In forcing its conclusion, the EPA had to ignore its own scientific guidelines. The EPA:

* did not follow accepted statistical principles;

* engaged in unjustified biological assumptions;

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* failed to give full consideration to "all relevant scientific information" and, indeed, omitted from consideration two of the most recent U.S. studies on lung cancer in nonsmokers;

* failed to thoroughly address alternative confounding factors, such as diet, occupational exposures and genetic dispositions;

* failed to "fully present" critical scientific data -- it didn't consider data on actual ETS exposures in public places, workplaces and the other venues. It didn't consider chemical-physical data on the differences between mainstream smoke and ETS; it ignored all the animal inhalation studies on tobacco smoke -- all of which fail to support EPA's contention;

* failed to "use the most scientifically appropriate interpretation to assess risk," in fact, it rejected one means of estimating risk because the method

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didn't generate any appreciable increased risk; and

* failed to acknowledge and describe uncertainties, assumptions and limitations in both the data and its interpretation.

I wish I could tell you that what the EPA has done about environmental tobacco smoke is unprecedented, that is just an aberration aimed at an unpopular target. But it's not. The EPA's history regarding dioxin, Alar, and asbestos indicates otherwise.

In the past, many have been skeptical of what we have had to say about environmental tobacco smoke. My only hope is that you will apply perhaps ten percent of the skepticism that

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you might reserve for me for the proponents of this standard. If you can go just that far, if your skepticism can take you into the issues then I'm confident that you will conclude that what the EPA and others want you to see is not what the science supports. What the EPA wants you to see is a risk assessment that no one but the tobacco interests will challenge, because it's about tobacco. And, it seems that virtually everyone is willing to believe virtually anything negative about tobacco without scrutiny.

Tobacco may be unpopular, and the science of ETS is quite complex. But in the courts and in regulatory proceedings, evidence must exceed the parameters of popular opinion. That's why we have sought judicial review of the EPA's risk assessment on ETS and that is why we urge you not to make

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regulatory decisions about smoking based upon the EPA's report.

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IBI Healthy Buildings International

Statement of Simon Turner
Healthy Buildings International Inc. (HBI)

Concerning the Issue Of Tobacco Smoke
in the Internal Environment

Testimony in Opposition to Proposed Regulation

Maryland
December 1993

I am a Director of Healthy Buildings International Inc. (HBI), a company that specializes in the study and assessment of indoor air quality. Since we incorporated in 1981, we have studied approximately 1,000 major buildings throughout the world. We serve our clients from five offices located in England, Australia, Spain, Canada and our headquarters office located in Fairfax, Virginia.

For twelve years our activities on behalf of our clients have been devoted to the study of indoor air problems. We analyze the air for fibers of textiles, asbestos, glass and mineral wools, radon, carbon monoxide, exhaust fumes, pesticides, detergents, carpet and furniture emissions, PCBs, volatile organic chemicals, bacteria, fungi and, of course, tobacco smoke. An integral part of our investigations is the study of the ventilation systems, their design, control sequences and operational policies. These experiences are all dedicated to cleaning up the indoor environment which makes our testimony especially relevant to any debate on these issues.

Sick Building Syndrome

We frequently investigate buildings on account of complaints from occupants with symptoms such as eye and nose irritation, fatigue, coughing, rhinitis, nausea, headaches, sore throats and general respiratory problems. It is frequently assumed by our clients that these symptoms are due to environmental tobacco smoke (ETS). However, it is clear that identical symptoms may be found in individuals exposed to formaldehyde, sulphur oxides, ammonia, oxides of nitrogen, and ozone. In addition similar symptoms are reported by those individuals with allergies to specific fungi such as *aspergillus*, *cladosporium*, and *penicillium* among others, as well as to miscellaneous bacterial aerosols. Overlapping symptoms also can be caused by exposure to household dusts, cotton fibers, fiberglass fragments, etc., and many of these symptoms are exacerbated as a result of an all too common problem of low relative humidities.

Energy Conservation

This complex of symptoms often described as "Sick Building Syndrome" may result primarily from energy conservation efforts to seal buildings and reduce the infiltration/exfiltration of air. Such efforts have reduced the natural infiltration of outdoor air that previously existed in many buildings, exacerbating the often undiscovered problem of a poorly designed or maintained HVAC system.

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Another energy conservation effort that may contribute to sick building syndrome is the recirculation of indoor air, at the expense of outdoor air. This may be a deliberate policy or shortsightedness on the part of the designers. This may result in the continuous redistribution of infectious microbes, allergenic dusts and spores from office to office and floor to floor. Improper ventilation can sometime be carried to extremes. Typically we find the outdoor air dampers were closed completely in approximately 20% of those buildings studied by HBI. All of these buildings were operating with 100% recycled indoor air. The lack of an adequate outdoor air supply, coupled with low air exchange rates, has led to unacceptable ventilation conditions in many of the buildings evaluated by HBI. Similarly, over 50% of the investigations conducted by NIOSH from 1978-1987 attributed the indoor air quality problems to inadequate ventilation, and similar results are found by investigations by other private concerns such as Honeywell, Inc.

The problem of poor ventilation in buildings is frequently compounded by other operation and maintenance problems, such as poor quality filters or sloppy filter installation. This can lead to serious hygiene problems inside air handling systems and ductwork. We have frequently seen thick layers of dirt inside air conditioning ductwork, along with fungi and bacteria growing in large numbers directly in the airstream being delivered to building occupants. However, it would be unfair to place all the blame at the feet of the property manager. Indeed, those property managers who are our clients should be commended for addressing the issue, usually on a proactive basis. Very often the occupants themselves, largely through inadequate education, create their own indoor air quality problems which range from careless placement and use of office equipment, to renovations and changes to their interior space which do not take into account the way in which the ventilation system is designed.

ASHRAE Standards

The American Society of Heating, Refrigerating and Air Conditioning Engineers (ASHRAE) is the world's foremost body responsible for developing and setting standards for engineers to use in the design and operation of heating, ventilating and air conditioning systems in all types of buildings. ASHRAE have set ventilation rates for most types of buildings, and for special use areas within the buildings. These ventilation rates are found in the ASHRAE Standard 62-1989, "Ventilation for Acceptable Indoor Air Quality". This standard was developed by consensus with engineers, architects, product manufacturers, health specialists and indoor air quality experts. The standard has recently been accepted by the American National Standards Institute (ANSI).

While there has been much controversy over the issue of smoking in commercial buildings, the position taken by ASHRAE acknowledges that any building adopting approved ventilation rates can accommodate typical indoor activities including a moderate amount of smoking. The standard ventilation rate prescribed in this standard for office areas calls for 20 cubic feet per minute (cfm) per person, assuming an occupant density of no more than seven people per 1000 square feet of space. Indeed, the occupants of a building complying with this standard will be experiencing air quality many times more acceptable than is the case of other buildings, with poor ventilation rates even in the absence of smoking. Designated smoking lounges should be ventilated at 60 cfm per person, using a mixture of supply air and air transferred from adjacent non-smoking areas.

The EPA's Statement on ETS

HBI is seeing an added influx of enquiries as a result of the Environmental Protection Agency's (EPA) recently published risk assessment concerning environmental tobacco smoke. We estimate that less than 40 percent of the 700 USA based buildings that we have studied allow smoking, and this number is dropping. However, I can categorically state that the air in 100 percent of them contain substances considered by the EPA as known or probable human carcinogens. Indeed, no less than 95

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percent contained the Group A carcinogen benzene. Others, including asbestos, radon, chloroform, trichloroethylene, carbon tetrachloride and styrene are found throughout the buildings we study. These are present regardless of whether smoking is allowed or banned.

Even if we assume that ETS was indeed a carcinogen, we must first recognize that the EPA has no statutory authority to regulate indoor air quality in the workplace. Such authority is in the hands of other agencies such as the Occupational Safety and Health Administration. Such agencies are experienced in dealing with carcinogens in any workplace. For example, OSHA uses Permissible Exposure Limits when they manage risks - including Group A carcinogens. These are typically 8 hour time weighted averages. In addition the American Conference of Governmental Industrial Hygienists use Threshold Limit Values (TLVs) for carcinogens, defined as concentrations of substances that nearly all workers may be exposed to, day after day, without any adverse health effects.

As an example, we can examine benzene which is classified as a Group A carcinogen. Standards for this compound range from 1 to 10 ppm, yet measurements of benzene in the home and in the workplace are about a thousand times lower than this, whether or not there is smoking activity. In fact, we have measured benzene in hundreds of offices in this country and found that there is more benzene in non smoking homes than in smoking offices. This is because there are so many sources of benzene in a typical home environment, and also because there is usually no ventilation in most homes. Our work has also been confirmed in a recent review of the literature which showed that there is more benzene in homes than in workplaces, and more again in transportation.

Another example is asbestos. OSHA sets a permissible exposure limit for asbestos of 0.2 fibers per cc of air, which means that a typical 100,000 square foot building could contain as many as five and a half billion fibers and it would still be judged as acceptable. And yet it is ironic that some people are suggesting that a few molecules of tobacco smoke indoors are grounds for evacuation of the building.

ETS in Ventilation Systems

Not only do we see that the levels of chemicals derived from ETS in the workplace are below OSHA standards, we have specific studies that report little or no ETS in air that has been recirculated in ventilation systems from smoking areas. First we have a recent study in Albuquerque restaurants. This study looked at a number of restaurants in the city that had smokers and non smokers simply separated by a short distance. According to this study, on average, you would have to sit in the non-smoking section of the restaurant for 1705 continuous hours to be exposed to the nicotine equivalent of a single cigarette. That is the same as eating out every single night, for two hours each, for two years and four months. Next, consider two other recent studies, both funded by anti-tobacco interests. The first, by Hayward et al, was conducted in California and paid for by the Cigarette and Tobacco Surtax Fund of the State of California. The second, by E. Light was conducted on the East Coast and was funded by the U.S. Public Health Services Region III Division of Federal Occupational Health. Both reported no detectable airborne nicotine in air that had been recirculated in ventilation systems from smoking areas. While it may be true that this does not mean that every trace of ETS is eliminated from the ventilation system, it does tell us something about the way in which ETS constituents tend to be contained in localized areas only. If we cannot even detect ETS, using state-of-the-art sensitive equipment, it is difficult to relate such measurements to any recognized health or comfort criteria.

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For these reasons if it is the goal of this committee to address the issues of clean indoor air it is imperative that you focus on the real issues. The proliferation of so-called "Clean Indoor Air Acts" which in reality are solely a polite phrase for smoking bans is unfortunate. How is it that cities with such acts still have Sick Buildings, still see buildings closed from PCB spills, schools suffering from fungal infestations, complaints of high absenteeism, even unacceptably high incidence of cross infections in hospitals etc.? Of course, consideration of smoking issues may well form part of a properly constructed Clean Indoor Air Act, but they are a small chapter, not the whole story.

The Building Systems Approach

In testimony such as this, it is easy to make negative statements about proposed regulation, and tougher to make constructive suggestions for alternatives. HBI along with many other companies and agencies, believe in a "building-systems" approach to indoor air quality. This involves the application of a number of ASHRAE standards and guidelines, including the recently adopted Standard 1962-89 regarding ventilation rates for acceptable indoor air quality. It requires the use of appropriate design criteria, construction documentation and the provision and implementation of building systems operation and maintenance procedures to ensure the health and comfort of building occupants. Such an approach is a more effective and economical approach to controlling indoor air quality than 'pollutant by pollutant' regulation. We believe that if you determine that regulatory action is needed to control indoor air quality, the approach should be via a pragmatic, effective and not onerous series of steps to enact a buildings systems approach. An objective review of the indoor air quality issue as it currently stands should lead you to the conclusion that the best way of achieving these goals is to take the following steps:

1) Recommend a ventilation standard for buildings similar to that established by ASHRAE Standard 62-89, "Ventilation for Acceptable Indoor Air Quality". This standard was developed and based on real-life feedback from architects, engineers, consumer organization, health officials, medical researchers, building owners, and operators and the interested public. With respect to the ventilation aspect of this standard, experience with IAQ in office settings is that 20 cfm of outside air per person is required for control of all indoor pollutants and that energy costs associated with this are not onerous. With respect to smoking, this ventilation rate deals adequately with moderate discretionary smoking activities in buildings. Should designated smoking areas be assigned, these should be ventilated at 60 cfm per person, using a mixture of supply air and air transferred from adjacent non-smoking areas. Our own extensive measurements have confirmed the adequacy of these rates.

2) Set standards on proper maintenance and selection of particulate and gaseous filters. Standards for better use of filters for protection from a health and comfort standpoint need to be developed. In the meantime, ASHRAE's recommended 40 percent efficiency standard or better (by the ASHRAE 52-76 dust spot test) should be adopted for commercial buildings. These should be carefully fitted and routinely serviced. This is based on our data which shows that of more than 1000 buildings worldwide examined over the past ten years, 43 percent fell below this recommendation and 16 percent were found to be poorly installed.

3) Set inspection protocols and standards for hygiene and maintenance practices in buildings. Other states such as Washington and New Jersey have adopted this, based on an annual or biannual inspection program. Such inspection programs exist for kitchens and other areas where hygiene is important.

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These steps embrace the "building systems" approach which we have supported for the past decade. Full acceptance of the building systems approach is, in our opinion, the most effective, practical and economic path to improved indoor air quality in all types of buildings.

What I have described in this testimony is a small part of presentations we make from time to time for professional groups around the world. These presentations are well accepted because they are based on common sense. If however, the tobacco industry asked us to present an identical presentation we are likely to be branded as apologists to that industry. We are not. We are a company that believes in describing conditions exactly as we find them. Today I appear before you at the request and expense of the Tobacco Institute. However, I assure you that my findings, statements and recommendations are based on our own independent research. Thank you for your time.

Simon Turner
Technical Manager
December 6, 1993

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Simon Turner is Technical Manager for Healthy Buildings International, Inc. (HBI) headquartered in Fairfax, Virginia, USA. Born and raised in southern England, Turner earned an HND in applied biology from Nottingham City University, England.

While working for the United Kingdom's National Nuclear Energy Research Group in Harwell (1980-1981), Turner studied the effects of radionuclide leaks from nuclear installations. From 1981 to 1982, he worked for Napp Laboratories, a major British pharmaceutical company.

Prior to joining HBI, Turner spent four years with the Atmospheric Sciences Division of the National Physical Research Laboratory in South Africa. There he conducted air pollution research in such fields as asbestos, acid rain, lead in gasoline and dust monitoring in heavily industrialized areas. Turner is the author of some 30 publications and technical reports on such topics.

In 1987, Turner joined HBI, a company devoted exclusively to the identification and control of internal pollution problems in public and commercial buildings. To date, HBI has diagnosed problems and specified solutions in over 147 million square feet (14 million square meters) of occupied space throughout the world. HBI has expanded its offices to Toronto, Canada; Sydney, Australia; Madrid, Spain; and London, England.

Turner is a member of the American Industrial Hygiene Association (AIHA) and the American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc. (ASHRAE). He is chairman of the Technical Committee of the Business Council on Indoor Air (BCIA) and he is on the Indoor Air Committee of the American Society for Testing and Materials (ASTM).

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NAME: Guy Simon Mark Turner

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SECONDARY AND HIGHER EDUCATION

September 1971 to July 1981 — The John Lyon School, Harrow, Middlesex (Public)

Six "O" Levels (English, Mathematics, Chemistry, Biology, Physics, Design and Technology)
One "A" Level (Biology)

Nottigham City University, Nottingham

Higher National Diploma in Applied Biology (three year thick sandwich course).
HND Dissertation: The distribution of radionuclides in the environment. Part 1 published as AERE Harwell report. See publication list.

EMPLOYMENT

June 1979 to October 1980 — Environmental & Medical Sciences Division
UK Atomic Energy Research Establishment
Harwell
Sandwich year under Dr P A Cawse

Activities:

Plant uptake of radionuclides - a literature review.
Radionuclide distribution studies on plants and soils: soil and crop sampling, soil grid survey, soil profile analysis, plant uptake experiments.
Trace element studies: atmospheric sampling, crop studies in urban areas.

September 1981 to July 1982 — Napp Laboratories
Medical Representative

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EMPLOYMENT (Con't)

September 1982
to December 1986

Atmospheric Sciences Division
National Physical Research Laboratory
Council for Scientific & Industrial Research
South Africa

Scientist Grade

Activities:

Trace element studies: atmospheric and workplace sampling.
Gas pollution studies with instrumented caravan.
Particulates in computer, switchgear, factory environments.
Vapor phase organic studies: activated carbon and tenax sampling at industrial sites.
Asbestos studies: sampling and counting with Transmission Electron Micrscopy.
Hydrogen fluoride studies: sampling and analysis with novel ion chromatographic method.
Meteorological studies: wind recording, tethersonde and pibal soundings.

January 1987
to present

Healthy Buildings International, Inc. (HBI),
Fairfax, Virginia, USA.
Technical Manager

Activities:

Management of HBI sales team
Development and marketing of new indoor air quality diagnostic systems.
Promotion of HBI services, represents HBI at seminars and conventions.
Quality control of indoor air quality diagnostic procedures and reporting.

MEMBERSHIPS:

Committee D22-05 (Indoor Air) of American Society for Testing and Materials
Air and Waste Management Association
American Industrial Hygiene Association
American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc.
Chairman, Technical Committee, Business Council on Indoor Air.

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TURNER, S. - Indoor Air Pollution - Sources, Effects and Mitigation Strategies. La Riforma Medica 3.91, Vol. 106, pp. 93-104, 1991.

TURNER, S., ROBERTSON, G.R. The Role of the New European Ventilation Guidelines in the Operation of US Buildings. Accepted for IAQ '93, Operating and Maintaining Buildings for Health, Comfort and Productivity. Philadelphia, November 7-10, 1993

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November 10, 1993

MEMORANDUM

A Maryland OSHA Smoking Ban Would be Illegal and Unjustified

The Maryland Occupational Safety and Health Administration ("MOSHA") is reportedly considering an occupational health standard regulating exposure to environmental tobacco smoke ("ETS") in the workplace. Initially, the State Secretary of Licensing and Regulation, William Fogle, reportedly advocated a complete prohibition on smoking to be effective in a matter of days. Wash. Post, Metro, D1 (Oct. 29, 1993).[1/] Apparently, MOSHA officials are not inclined to pursue an emergency regulation, but have begun the process of promulgating a permanent occupational health standard for ETS. Wash. Post, Metro, C2 (Nov. 4, 1993).

However, a Maryland Occupational Safety and Health ("MOSH") standard for ETS would be premature and inconsistent with ongoing federal Occupational and Safety Health Administration ("fed-OSHA") initiatives. The federal Occupational Safety and Health Act ("federal OSH Act") also prohibits Maryland from enacting a health standard regulating ETS. In addition, a workplace smoking regulation would not satisfy Maryland Occupational Safety and Health Act ("MOSH

[1/] The State Secretary of Licensing and Regulation has no power to regulate ETS. Only the Commissioner of Labor and Industry has the authority to enact state occupational safety and health regulations. Md. Lab. & Emp. Code Ann. § 5-201.

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Act") requirements and would have a disproportionate economic impact on small businesses and on businesses who provide services to customers who smoke.

1. A MOSH Standard Would be Premature and Inconsistent with Federal OSHA Initiatives.

Fed-OSHA is actively considering whether to promulgate a standard regulating smoking in the workplace. To date, however, OSHA has found insufficient evidence of significant risk to employees to justify regulation of smoking in the workplace.

In 1989, federal OSHA denied a petition filed by Action on Smoking and Health ("ASH") for an emergency temporary standard to ban smoking in the workplace. In December 1991, in response to a lawsuit filed by ASH in the United States Court of Appeals for the District of Columbia Circuit, fed-OSHA stated that it "still does not have adequate information on the current level of exposure to [ETS] in workplaces to accurately assess the existing level of occupational risk." The D.C. Circuit upheld OSHA's decision not to promulgate an emergency standard on ETS. ASH v. OSHA, No. 89-1656 (D.C. Cir. May 10, 1991).

In 1991, OSHA initiated a Request for Information on Occupational Exposure to Indoor Air Pollutants ("RFI") in order to collect all available data regarding the full range of potential indoor air pollutants, including ETS. OSHA has evaluated the comments to the RFI, commissioned further research concerning the possible health effects of ETS, and is

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actively studying possible regulation of indoor air quality, including smoking restrictions. In view of fed-OSHA's activity in this area, a MOSH standard would be premature.

In addition, fed-OSHA's attention and focus on indoor air quality in the workplace would render any MOSH rulemaking on workplace smoking duplicative and inefficient. Any standard that fed-OSHA ultimately adopts for indoor air quality or ETS will, in turn, have to be adopted by MOSH, in accordance with the full notice-and-comment requirements of the Maryland Administrative Procedures Act.[2/] 29 U.S.C. 667(c)(2). Thus, given the ongoing fed-OSHA initiative on indoor air quality, it would be a complete waste of state resources for MOSH to undertake a rulemaking on workplace smoking.

2. A MOSH ETS Standard Would Violate Federal OSHA Requirements

Maryland is a "Plan State" that, pursuant to section 18(c)(2) of the federal OSH Act, shares responsibility with fed-OSHA for the regulation of occupational safety and health issues. 29 U.S.C. 667(c)(2). Under this grant of authority, the State is precluded from regulating more stringently "products which are distributed or used in interstate commerce" and subject to a federal standard unless the State can demonstrate that the regulations are required by "compelling local conditions" and do not unreasonably burden

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2/ Md. State Gov't Code Ann. §§ 10-110, 10-111.

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interstate commerce. Id.; Florida Citrus Packers v. California, 549 F. Supp. 213, 215 (N.D. Cal. 1982).[3/]

Fed-OSHA has taken the position that this restriction applies with equal force when a Plan State seeks to regulate in an area that is not addressed by a federal standard.[4/] Tobacco products clearly are products "distributed or used in interstate commerce." Thus, Maryland is prohibited from regulating smoking in the workplace unless it can show that state regulations are required by compelling local conditions and do not unreasonably burden interstate commerce.

Maryland cannot satisfy this standard. A MOSH smoking ban would unreasonably burden interstate commerce in

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[3/] See also Md. Lab. & Emp. Code Ann. § 5-309(a)(2)(i-ii). Maryland law provides that the Occupational Safety and Health Advisory Board ("Board") shall propose standards that "will not put an undue burden on interstate commerce when:

> (i) a local condition or customized product or part requires the application of an occupational safety and health standard that differs from a federal standard; and
>
> (ii) applied to a product or part that is distributed or used in interstate commerce."

Id.

[4/] See, e.g., 57 Fed. Reg. 56378 (Nov. 27, 1992) (federal OSHA notes that a proposed Washington OSHA standard has no counterpart in federal OSHA regulations, but nonetheless seeks comment on whether it violates the products clause); 52 Fed. Reg. 28878 (Aug. 4, 1987) (same for a proposed Wyoming OSHA standard); 57 Fed. Reg. 32020 (July 20, 1992) (federal OSHA approves a proposed Oregon OSHA standard for which no corresponding federal OSHA standard exists, in part because the products clause is satisfied); 56 Fed. Reg. 26842 (June 11, 1991) (same for proposed Oregon OSHA standard).

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tobacco products by prohibiting their use by individuals at work and in establishments like bars, restaurants, and hotels. Moreover, there has been no showing that more "compelling local conditions" exist in Maryland, as compared to any other state, that would justify banning the use of tobacco products in the workplace. Therefore, under federal OSHA, Maryland has no authority to regulate smoking in the workplace.

3. A Workplace Smoking Ban Would Not Satisfy MOSH Act Requirements.

To adopt a state OSH regulation, the Commissioner must comply with the requirements of MOSH and the Maryland Administrative Procedure Act ("APA").[5/] Md. Lab. & Emp. Code Ann. § 5-312.

[5/] Md. State Gov't Code Ann. §§ 10-110, 10-111. The MOSH Advisory Board ("Board") has the responsibility for proposing reasonable regulations to prevent conditions that are detrimental to safety and health in employment and that the Board finds are necessary to protect and to improve the safety and health of employees. Md. Lab. & Emp. Code Ann. § 5-308. The Board may conduct necessary public hearings, but no hearing is required if there is an identical regulation enacted by another State governmental unit, a national standard-setting organization, or fed-OSHA. The Board has announced public hearings on the proposed ETS regulation for December. Wash. Post, Metro, C2 (Nov. 4, 1993).

If the Commissioner accepts the Board's recommendation to adopt a proposed regulation, he must initiate the notice-and-comment process of the Maryland APA within 45 days of the Board's recommendation. The proposed regulation must be submitted to the Joint Committee on Administrative, Executive, and Legislative Review ("Committee") for Preliminary Review, published in the Maryland Register, and public comment opportunities provided. Md. State Gov't Code Ann. § 10-111.

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A. Emergency Regulation

The Commissioner may issue an emergency regulation only where it is "needed to protect employees from the grave danger" of a "new hazard" or exposure to a toxic or physically harmful agent. Md. Lab. & Emp. Code Ann. § 5-314(a)(1-2). The Commissioner must declare that the emergency regulation is necessary and must submit the proposed regulation to the Joint Committee along with a fiscal impact statement. Md. State Gov't Code Ann. § 10-111(b). The Committee must then approve the regulation, which remains in effect for the period of time set by the Committee or alternatively, for a maximum of six months. Id.; Md. Lab. & Emp. Code Ann. § 5-314(b).

This is the same statutory requirement as the federal OSH Act. 29 U.S.C. 655(c). Under this standard, fed-OSHA has refused to promulgate an emergency regulation for ETS because "the available data are not sufficiently definitive in certain critical areas to support the need for an [emergency regulation], particularly in light of the extremely stringent statutory criteria for issuing and sustaining such an action."[6/] Emergency regulation is an "extraordinary" remedy

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6/ Letter from OSHA to ASH, Sept. 1, 1989. This decision was upheld by the D.C. Court of Appeals. ASH v. OSHA, No. 89-1656 (D.C. Cir. May 10, 1991).

In every reported case involving a federal OSHA emergency standard, the reviewing court has either affirmed the Secretary's decision not to promulgate a standard, In re Int'l Chemical Workers Union, 830 F.2d 369, 372 (D.C. Cir. 1987) (cadmium), Public Citizen Health Research Group v. Auchter, 702 F.2d 1150, 1155 (D.C. Cir. 1983) (ethylene oxide), United Automobile Workers v. Donovan, 590 F. Supp. 747, 750 (D.D.C.

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that is appropriately applied only as "an unusual response to exceptional circumstances." In re Int'l Chemical Workers Union, 830 F.2d 369, 370-71 (D.C. Cir. 1987); Taylor Diving & Salvage Co. v. Department of Labor, 537 F.2d 819, 820 (5th Cir. 1976). Fed-OSHA has repeatedly found that ETS does not require this "unusual response."

There is no legal basis for a Maryland emergency regulation in view of fed-OSHA's determination that there is insufficient evidence of a grave danger to employees caused by ETS in the workplace.

B. Permanent Regulation

For Maryland to regulate ETS on a permanent basis, it must show that regulation is "reasonably appropriate or necessary" to make employment safe and healthful.[7/] Md. Lab. & Emp. Code Ann. § 5-101(e)(1-2). Again, this is the same statutory requirement of the federal OSH Act that the proposed standard be "reasonably necessary or appropriate". 29 U.S.C.

[6/](...continued)
1984), vacated the standard, Florida Peach Growers Ass'n v. Department of Labor, 489 F.2d 120, 129 (5th Cir. 1974) (organophosphorus pesticides); Dry Color Manufacturers' Ass'n v. Department of Labor, 486 F.2d 98, 101 (3d Cir. 1973) (14 chemical carcinogens), or stayed the standard's effect, Asbestos Information Ass'n v. OSHA, 727 F.2d 415, 426 (5th Cir. 1984) (asbestos); Taylor Diving & Salvage Co. v. Department of Labor, 537 F.2d 819, 820 (5th Cir. 1976) (diving operations).

[7/] The Board is directed to propose "reasonable regulations" that prevent conditions that are "detrimental" to safety and health in employment and that the Board finds are "necessary " to protect and improve the safety and health of employees. Md. Lab. & Emp. Code Ann. § 5-308.

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§ 652(8). American Textile Manufacturers v. Donovan, 452 U.S. 490, 506 (1981); Industrial Union Department, AFL-CIO v. American Petroleum Institute, 448 U.S. 607, 614-15, 639, 642-43 (1980) (plurality opinion).

Fed-OSHA, as indicated previously, has not yet issued a health standard on ETS because it has concluded -- and the D.C. Circuit Court has concurred -- that insufficient data exists to render a workplace ETS standard "reasonably necessary." Moreover, in determining whether a smoking ban is "necessary," MOSHA must consider other feasible alternatives. See, e.g., Dry Color Manufacturers, 486 F.2d at 107. Options such as separating smokers and non-smokers and improving ventilation will reduce workers' exposure to ETS without ignoring the interests of smoking employees and customers. Therefore, MOSHA cannot establish a smoking ban in the workplace is "reasonably appropriate or necessary."[8/]

4. A Smoking Ban Would Have a Detrimental Impact on Small Businesses.

The Maryland Administrative Procedure Act requires MOSHA to evaluate the impact on small businesses before

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8/ Maryland law requires the Board to develop OSH standards for toxic materials or harmful physical agents "that most adequately ensure, to the extent feasible on the basis of the best available evidence, that no employee, including an employee who has regular exposure to [these agents] during the working life of the employee will suffer material impairment of health or functional capacity." Md. Lab. & Emp. Code Ann. § 5-309(c). The scientific evidence does not show that there is a significant risk of material impairment of an employee's health from exposure to ETS in the levels typically encountered in work environments. Thus, a smoking ban would not be justified under this standard.

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adopting any regulation of ETS. Md. State Gov't Code Ann. § 10-124(b). MOSHA must evaluate the impact on the basis of the size of the business and must particularly consider the costs of a regulation and the difficulty of compliance for each class of business. Id. Under the MOSH Act, an employer is defined as anyone employing at least one person. Md. Lab. & Emp. Code Ann. § 5-101(d). Thus even the smallest businesses would be subject to an ETS regulation.

Any smoking ban would have a grossly disproportionate impact on small businesses. In very small businesses, a ban on smoking effectively would force employees to close shop in order to go outside to smoke. In addition, such a regulation would impose a particularly heavy strain on a small business owner's relationship with his customers.

Furthermore, businesses that traditionally service smoking customers will be disproportionately effected by regulation of ETS. Nightclubs, hotels, convention centers, and coffee shops will suffer a significant reduction in business if smoking is banned in those establishments.

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A MARYLAND OSHA SMOKING BAN WOULD BE ILLEGAL AND UNJUSTIFIED

The Maryland Occupational Safety and Health (MOSH) Advisory Board has asked for comment on a proposed regulation that would ban smoking by employees in any place of employment. The proposed regulation should be rejected.

The proposed regulation is unreasonable

The proposed regulation would require every employer **"to ensure that an employee, while in the place of employment, does not smoke."**

- The proposed rule thus appears to make the employers responsible for the personal behavior of their employees even if the employer, as a practical matter, cannot exercise control over the behavior of the employee.
  - Employers located in other states would have to ensure that their employees refrain from smoking while working in Maryland – even if no supervisor is present to monitor the employee.
  - Maryland employers whose employees work without direct supervision (e.g., employers who employ sales or service representatives) would similarly be responsible for ensuring that their employees refrain from smoking.
- The proposed rule apparently applies even to smoking by employees at outdoor worksites (e.g., a street-sweeper, a construction worker, a hot dog vendor, a telephone lineman, a meter reader).
- The proposed rule apparently applies even to employees who are working by themselves (e.g., a truck driver, a sales representative) or who are working with other smokers or consenting nonsmokers.

The proposed regulation would be precipitous and violate the federal OSH Act

The U.S. Occupational Safety and Health Administration (OSHA) currently is evaluating information on environmental tobacco smoke (ETS) and is considering possible workplace smoking restrictions. A Maryland smoking ban would be precipitous in light of the ongoing federal OSHA review and would improperly usurp federal OSHA authority over indoor air quality issues.

Federal OSHA has the expertise and resources needed to assess the need for regulation. Indeed, under the federal OSH Act, Maryland is precluded from regulating smoking in the workplace unless it can show that its regulation is required by "compelling local conditions" and does not unreasonably burden interstate commerce. MOSH cannot make that showing.

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The proposed regulation would not satisfy the Maryland OSH Act

A workplace smoking ban would not satisfy the legal requirements of the Maryland Occupational Safety and Health Act. There is insufficient evidence of "significant risk" to employees under actual workplace conditions to justify a smoking ban. In the past several years, federal OSHA has on two occasions specifically declined to regulate smoking based on the inadequacy of available data on ETS exposure in the workplace.

The federal EPA report on ETS does not justify a workplace smoking ban

EPA did not conduct original research. It reviewed and then cherry-picked and "reinterpreted" studies done by others. EPA adjusted science to suit policy.

- **EPA manipulated the data to achieve predetermined results**

Of the 30 studies from around the world that EPA examined, 24 – or 80 percent – reported no statistically significant overall association between ETS and increased risk of lung cancer in nonsmokers. Of the 11 studies from the U.S. considered by EPA, not a single one originally reported a statistically significant overall increased lung cancer risk. Only by relaxing its normal standards was EPA able to arrive at the conclusion that there is a statistically significant association between ETS and risk of lung cancer.

- **EPA ignored data inconsistent with its predetermined conclusions**

EPA refused to consider two major ETS epidemiological studies published in 1992 that are inconsistent with its conclusions about ETS and lung cancer. These studies include one of the largest U.S. studies ever conducted, sponsored in part by the National Cancer Institute. When these studies are included in a combined analysis of the U.S. studies that EPA considered, there is no statistically significant increased risk of lung cancer even using EPA's relaxed standards.

- **EPA relied entirely on studies of spousal smoking**

EPA based its conclusions about ETS and lung cancer entirely on studies of reported spousal smoking in the home. Federal OSHA has made clear that quantitative risk estimates for workplace smoking cannot be extrapolated from residential studies and that proper evaluation of the risks of ETS exposure to workers must be based on actual workplace conditions.

- **EPA ignored relevant workplace smoking studies**

EPA ignored the important and large data base of 14 studies that have reported lung cancer risks for workplace exposure to ETS. The workplace studies report no statistically significant overall lung cancer risk to nonsmokers from ETS exposure.

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EPA's classification of ETS as a Group A carcinogen generates no general duty to eliminate ETS exposure. A number of common substances designated by EPA as Group A carcinogens, such as benzene, are not banned, but, rather, are subject to permissible exposure levels set by OSHA.

Elimination of ETS will not prevent exposure to the substances that make up ETS, which have a variety of indoor sources – including furniture, carpets, cooking and other processes. Exposure to ETS can be adequately controlled through proper ventilation and reasonable segregation of smokers and nonsmokers.

The proposed regulation is an end-run around the Legislature

Unlike other matters considered by the Board, a regulation banning smoking in the workplace would broadly restrict personal employee behavior and would have wide social implications. Public smoking has been the subject of extensive consideration by the Legislature, which has enacted laws prohibiting and restricting smoking in a number of places.

In 1990, 1991 and 1992 bills were introduced to address smoking in workplaces and other public settings. The Legislature declined to act, leaving the issue for private resolution. In September 1993, the Environmental Affairs Committee of the House of Delegates held an oversight hearing on public smoking in preparation for considering the issue again in 1994.

As stated earlier, federal OSHA is the appropriate agency to address workplace smoking. But it would be particularly ill-advised for the Board to adopt a workplace smoking rule just as the Maryland Legislature is preparing to consider the matter again to determine what action may be warranted in the future.

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SUMMARY OF TOBACCO INSTITUTE CRITICISMS OF EPA RISK ASSESSMENT

EPA's treatment of environmental tobacco smoke -- the smoke to which a nonsmoker may be exposed -- is without Agency precedent.

EPA uses a questionable approach to reach its conclusions. The document suggests the plausibility of its conclusions by pointing to an assumed similarity between ETS and mainstream smoke -- that which the smoker inhales -- even though the report indicates they are different.

- The report concedes substantial physical and chemical differences between the mainstream tobacco smoke to which smokers are exposed and the ETS to which nonsmokers may be exposed. The report also concedes enormous differences in the levels and routes of exposure. Never before has EPA ignored such differences in proposing to classify a substance as a Group A carcinogen.

- An untenable precedent is set by classification of ETS as a Group A carcinogen based on comparisons of the smoke to which a smoker is exposed and nonsmoker ETS exposure. If containing any of the same substances as mainstream smoke is a sufficient basis for such a classification, then the air in every building and home might qualify as a Group A carcinogen. Water, hamburgers, peanut butter and many other everyday products and foods also could qualify.

The majority of the lung cancer studies, including the most recently published ETS/lung cancer study -- one of the largest ever conducted -- report no statistically significant increase in risk.

- If the most recent studies are added to EPA's lung cancer data base, the risk assessment's overall risk for EPA's report would be statistically nonsignificant.

- Over two-thirds of the studies reviewed in the EPA document do not report a statistically significant association between exposure to ETS and lung cancer among nonsmokers. Never before has EPA proposed to classify a substance as a Group A carcinogen on the basis of such weak and inconclusive data.

- EPA acknowledged earlier that the U.S. studies do not convincingly support the contention that ETS exposure increases nonsmoker lung cancer risk. To reach a contrary conclusion, this report adopts lowered standards and statistical devices.

- The report ignores workplace and male exposure data -- data that do not indicate an association between exposure to ETS and lung cancer -- apparently because the majority of these data do not fit the report's conclusion.

The EPA report also discusses respiratory disorders in children. The first draft document acknowledged that the pertinent studies were too equivocal to support a causal inference. In contrast, the final report selectively reviews the studies and fails to account for many of the flaws and inconsistencies it had earlier acknowledged.

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IMPORTANT QUESTIONS ON EPA'S RISK ASSESSMENT ON ENVIRONMENTAL TOBACCO SMOKE (ETS)

1) **Given the Agency's longstanding credibility problems, including those recognized recently by an expert panel convened by the previous Administrator, how could EPA release a report that is not supported by the majority of the studies on lung cancer that were reviewed?**

- Of the 30 lung cancer studies reviewed by EPA, 24 do not report statistically significant increases in risk.

- The Administrator's expert panel, in a report entitled "Safeguarding the Future: Credible Science, Credible Decisions," found that "EPA science is of uneven quality and the Agency's policies and regulations are frequently perceived as lacking a strong foundation." The panel also noted that "science should never be adjusted to fit policy, either consciously or unconsciously."

2) **Isn't it true that of the 11 U.S. lung cancer studies reviewed by the EPA, not one originally reported an overall statistically significant increase in risk?**

- EPA acknowledged previously that the U.S. studies do not convincingly support the contention that ETS exposure increases nonsmoker lung cancer risk. EPA lowered its statistical standard to reach a contrary -- politically correct -- conclusion.

- The statistical standard in question involves EPA's novel use of a 90 percent confidence interval. Generally accepted conventions require the use of a 95 percent confidence interval. Weakening this standard is the equivalent of a bell-curve in test grading -- the standard is lowered to achieve the desired result.

3) **Isn't it true that the most recent ETS study published, one of the largest studies to date and funded by the National Cancer Institute, reported no over-all statistically significant increase in risk?**

- This study, published in November 1992 in the American Journal of Public Health, reported no over-all statistically significant increase in risk between lung cancer and reported ETS exposure.

- In fact, the majority of the most recent ETS studies fail to demonstrate a statistically significant association between ETS and nonsmoker lung cancer. Many scientists have pointed out that these newer studies are larger and better designed than previous studies.

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4) **If the ETS studies published since the EPA's review were included, wouldn't the conclusions be dramatically different?**

- Yes. If the data from the two new published studies were included, the EPA's meta-analysis of U.S. studies would not be statistically significant.

5) **Doesn't one of the approaches of the risk assessment -- using the smoke to which a smoker is exposed to suggest the plausibility of the claim that ETS is a Group A carcinogen -- set an untenable precedent?**

- The report concedes substantial physical and chemical differences between the mainstream smoke to which smokers are exposed and the ETS to which nonsmokers may be exposed. The report also concedes enormous differences in the levels and routes of exposures.

- Classification of ETS as a Group A carcinogen based on comparisons of the smoke to which a smoker is exposed and nonsmoker ETS exposure, sets an untenable precedent. If the fact that something -- in this case ETS -- contains any of the same substances as mainstream smoke was the basis for a "Group A" label, then the air in every building and home, drinking water, hamburgers, peanut butter and many other every day products could also be classified Group A.

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SCIENTIFIC AND MEDIA COMMENT ON THE EPA'S ETS REPORT

In January 1993, the Environmental Protection Agency issued its final report classifying environmental tobacco smoke (ETS) as a "Group A" carcinogen. Experts and commentators found not only a lack of credibility in the report itself but also in EPA research generally and in what some of them felt the EPA action portends.

While The Tobacco Institute does not necessarily agree with everything in the articles cited, we think they do outline a number of the scientific deficiencies in the EPA report.

"The EPA's recent declaration that ETS is a 'Class A carcinogen' was achieved by a quite shameless abandonment of regular scientific procedures."

- National Review, 4/12/93.

"[The EPA study] simply ignored the inconvenient results and emphasized those that are in a memorable term 'helpful'."

- Professor Alvan Feinstein, Yale University medical school, Toxicologic Review, 1993.

"More important than the smoking issue, however, is the dangerous precedent being set. If government scientific findings do not adhere to traditional and rigorous scientific methods, then they will represent nothing more than the political leanings of those wielding a malleable tool."

"As a non-smoker who intensely dislikes the smell of other people's fumes, and as the father of a newborn daughter, I have strong objections to having my family subjected to secondary smoke. Yet, ironically, I cannot in good conscience condone EPA's crusade."

- John Shanahan, Phoenix Gazette, 12/7/92.

"If it (the EPA) can skew science on ETS and get away with it, then what happens when another substance is deemed politically incorrect?"

- Richmond Times-Dispatch, 1/11/93.

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"To establish secondhand smoke as a killer of 3,000 hypothetical Americans, the EPA had to ignore the antithetical findings of a study sponsored by the National Cancer Institute. William Reilly, head of the EPA, claimed his report was too far along to take into account those findings, but had he done so, his report would not have been able to claim secondhand smoke as a carcinogen."

- R. Emmett Tyrrell, Jr., New York Post, 2/5/93.

"In truth, this report is another example of the EPA shaping scientific findings to support its own preconceived policies."

- R. Emmett Tyrrell, Jr., The Washington Times, 2/7/93.

"There's nothing wrong, of course, with government trying to promote the general welfare. But using tax dollars to finance questionable government efforts to undermine the interests of those engaged in legitimate business does not further this constitutional mandate."

- Jerry Heaster, The Kansas City Star, 1/30/93.

"If smoking is to be the object of a crusade, make it a good, old-fashioned political crusade. Don't pervert the science to justify the politics."

- John Mark, Phoenix Gazette, 1/12/93.

"The Environmental Protection Agency today will foster yet another hoax on the American people as it begins a campaign of public misinformation on the hazards of secondhand smoke."

- Kingsport Times News, TN, 1/7/93.

"The designation will substantially increase pressure to curb smoking in many, if not most, buildings. That might not be a bad goal, except that the methods employed by EPA to achieve it were scientifically underhanded."

"It is to say that EPA has once again undermined what shred of confidence may remain about its reliability. You may have little sympathy with the tobacco companies, but who will be next on the EPA hit list?"

- The Detroit News, 1/14/93.

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"I did work for the EPA in the past and thought of them reasonably well, but when I saw that report, I was really embarrassed. It was a bad document."

- Alfred P. Wehner, president, Biomedical and Environmental Consultants, Inc., Investor's Business Daily, 1/28/93.

"In most cases, a scientist would never do this sort of thing (double the probability of a result occurring by chance). It's surprising they would try to get away with it."

"They're (EPA) using it so they can get an effect. They're going all out to get something they can call significant."

"To me it's frightening that they could make such a case out of such a small risk factor when you've got so many variables."

- James Enstrom, professor of epidemiology, UCLA, Investor's Business Daily, 1/28/93.

"You cannot run science with the government changing the rules all the time."

- Michael Gough, program manager for biological applications, Office of Technology Assessment, Investor's Business Daily, 1/28/93.

"EPA science is of uneven quality, and the Agency's policies and regulations are frequently perceived as lacking strong scientific foundation."

"Science should never be adjusted to fit policy."

- Scientific panel, Safeguarding the Future: Credible Science, Credible Decisions, 1992.

"EPA's finding is a clear example of bad science being used to justify politically correct policy. The agency reviewed 11 American studies of spouses of smokers. In 10 of the studies, researchers found no statistically significant increases in cancer, and in one they did."

- Joseph Perkins, The Washington Times, 3/19/93.

"The EPA's findings provide fodder for those who would sharply curtail, or even outlaw, the right of an individual to smoke. But such government meddling is unnecessary."

- Las Vegas Review Journal, 1/13/93.

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"Those of us who are occasionally exposed to the emissions of smokers may find their proximity annoying or even impolite. But it is hardly necessary to empower federal regulators and dispose of scientific standards in order to address the issue. Common sense, good manners, and voluntarily created 'smoking areas' are infinitely preferable to the keystone commissars at EPA."

- Matthew Hoffman, analyst, Competitive Enterprise Institute, The Washington Times, 7/1/93.

"If the EPA's analysis had employed a 95 percent confidence interval, as most of the studies it incorporated did, it would have found no overall statistically significant connection between ETS and lung cancer."

"The EPA's disregard for scientific standards threatens to open up homes and offices to costly and intrusive regulations, and creates a precedent that might be used to indict other aspects of our living environment."

- Matthew Hoffman, Colorado Leader, Denver County, 3/27/93.

"Let me remind you that the relative risk we are talking about here (chlorinated water) is higher than the relative risk for environmental tobacco smoke. The difference is that nobody likes environmental tobacco smoke. It's kind of easy. It's easy for people to say, 'Oh, let's get rid of that smoke; it's really nasty and horrible,' but in fact, the relative risk we are talking about here in the highest exposed group in [Ken Kantor's] study was higher than the relative risk, for the average, for lung cancer for someone married to a smoker. Think about that."

- Dr. Devra Lee Davis, National Academy of Sciences, 11/4/92.

It's easy to see why some scientists are concerned that the EPA report is being used, unjustly, to pave the way for new government regulations. Regulations, in fact, which might not only be unnecessary, unsound and unwarranted, but also unenforceable."

- Tribune-Review, Greensburg, PA, 3/1/93.

"Mr. Reilly's regulatory passion shows constantly. What we have at the EPA might be called political science -- science you shape and bend to fit a social agenda."

- William Murchison, Dallas Morning News, 12/20/92.

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"The looseness of the scientific standards of EPA's report and its exaggeration of the risks associated with passive smoke raise once again questions about what is happening to scientific ethics."

- Citizen News, 3/3/93.

"Now that the EPA has lowered the standard of risk, not only can second-hand smoke be classified as a cancer risk but so can ordinary tap water, whose risk factor is twice that of second-hand smoke."

- The American Spectator, April 1993.

"The EPA's edict on ETS was accompanied by a weighty tome of junk science, in which almost every known statistical confidence trick is on display."

"By the scandalously manipulative standards of the ETS case, the EPA could move immediately to ban chlorination of drinking water, order massively expensive reorganization of electricity service lines (because of the speculative dangers of electro-magnetic fields), and outlaw diesel vehicles and heating systems that use number 2 home heating oil. In all these cases there are already statistical studies that produce risk numbers at least as strong as those used to indict ETS."

- National Review, 7/19/93.

"Excessive regulation and poor science make terrible government. If the suit filed last week prevails [June 22, 1993, suit against EPA filed in federal district court by six tobacco organizations] we will have reached the pass at which the tobacco industry has greater credibility on this health issue than the EPA. That would speak volumes about the state of government 'science' and those volumes will be useful to smokers and nonsmokers alike."

- The Washington Times, 6/29/93.

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Investor's Business Daily
"The Newspaper For Important Decision Makers"
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NATIONAL ISSUE

IS EPA BLOWING ITS OWN SMOKE?

How Much Science Is Behind Its Tobacco Finding?

By Michael Fumento
In Los Angeles

"Taken together, the total weight of evidence is conclusive that environmental tobacco smoke increases the risk of lung cancer in nonsmokers."

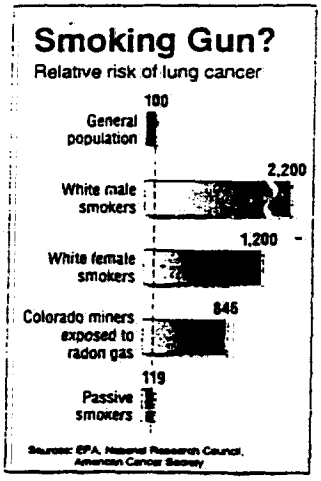
So declared Environmental Protection Agency Administrator William Reilly at a news conference earlier this month, announcing the impending release of an EPA report attributing approximately 3,000 deaths a year to passive smoking, or environmental tobacco smoke.

Yet many in the scientific and medical community say the data the EPA cites does not bear out its conclusion.

While virtually all scientists agree that smoking is unhealthful -- both for smokers and those around them -- it's the degree to which smoking is unhealthful, and the way the government musters its scientific case, that raises questions.

Some scientists and policy analysts who say they couldn't care less about tobacco company profits or even the rights of smokers are worrying aloud that the EPA report is paving the way for justifying new health-based government regulations and programs without any real science behind them.

Said Bonner Cohen, editor of EPA Watch based in Chantilly, Va., "It's now open season on whatever contaminant the EPA chooses to label the killer contaminant of the week, with the effect that once again, Americans are going to be stampeded into fearing a substance for reasons which upon close inspection are scientifically indefensible."



Yale University epidemiologist Alvan Feinstein, writing in the journal Toxicological Pathology, said he recently heard a prominent leader in epidemiology admit of the EPA's work on passive smoking: "Yes, it's rotten science, but it's in a worthy cause. It will help us to get rid of cigarettes and to become a smoke-free society."

Another critic, Alfred P. Wehner, president of Biomedical and Environmental Consultants Inc., in Richland, Wash., said: "I did work for the EPA in the past and thought of them reasonably well, but when I saw that report, I was really embarrassed. It was a bad document."

One thing both sides agree on is that the direct policy ramifications of the EPA report could be tremendous.

"You can bet your next paycheck that OSHA (the Occupational Safety and Health Administration) will ban all smoking in the workplace," said John Shanahan, the environmental policy analyst at the Heritage Foundation.

Although, in unveiling the report, Reilly expressly referred to cancer in children and in the workplace, the statistical analysis in the EPA report actually ignored the studies that looked for such links.

Rather, the EPA survey is based on 11 American studies of spouses of smokers. The report discussed, but did not put into its statistical analysis, the results of 19 other studies done outside the U.S.

In its analysis of those 11 studies, the EPA found that there was a "statistically significant" difference in the number of lung cancers suffered by nonsmoking spouses of smokers, equal to 119 such cancers in nonsmoking spouses of smokers compared to 100 lung cancers in nonsmoking spouses of nonsmokers.

This finding of statistical significance allowed it to rank passive smoking as a Class A carcinogen, the highest risk ranking possible.

Statistical significance, while sounding like arcane academic talk, is actually quite important. It is used to account for the possibility that something happened -- in this case the 19 additional lung cancers -- by chance.

But critics say that, using its own previous statistical standards, the EPA report shows no such significance.

"Frankly, I was embarrassed as a scientist with what they came up with. The main problem was the statistical handling of the data," said Wehner, who headed a panel of scientists and doctors that analyzed the draft version of the EPA report for the tobacco industry.

'Meta-Analysis'

One aspect of this problem, say critics, involves the combination of the 11 studies into *one* big group — what the EPA called a "meta-analysis."

The EPA has never before done this. Critics say such combinations may be valid, but if the studies weren't done in the same way, the results will be like comparing apples and oranges and pears.

Not everyone agrees.

"Meta-analysis is totally fair," said Stanton Glantz of the Institute of Health Policy Studies at the University of California, San Francisco. "I review reports like that for the State of California, and the work the EPA did is absolutely first rate, one of the best pieces of science I've seen about anything."

But Wehner said the study was faulty.

"To get scientifically valid data, there are very strict rules and requirements on how and when you can apply meta-analysis, and virtually all of them were violated in the EPA analysis," he said.

'Confidence Intervals'

The 11 studies together actually reflected 10 studies that showed no statistically significant increases in cancer and only one that did. When the EPA says that the weight of 11 studies showed harm from passive smoking, it really meant one positive combined with 10 neutrals.

More important than the use of the meta-analysis, say critics, is the EPA's use, also for the first time, of a less rigorous statistical analysis.

Epidemiologists -- those who study disease and accident patterns to establish why they occur — calculate "confidence intervals" to express the likelihood that a result could have happened strictly by chance.

A 95% confidence interval means that there is a 95% possibility that the result didn't happen from chance, or a 5% possibility that it did.

Until the passive smoking report, the EPA has always used a 95% confidence interval, as have most researchers doing epidemiological studies. Indeed, all of the individual ETS studies were published with 95% confidence intervals.

Yet, in its averaging of those ETS studies, the EPA decided to go with a 90% confidence interval.

"That doubles the chance of being wrong," explained James Enstrom, a professor of epidemiology at the University of California, Los Angeles.

Reilly said simply: "With respect to the confidence interval, we have here a 90% confidence level. And that was, in fact, what was recommended to us by the scientific community as appropriate to this data." Repeated calls to the EPA to find out who in the scientific community had done so went unanswered.

'Hairsplitting' Factor

Glantz said the criticism of the change in the confidence level is a kind of "hairsplitting that only professors care about."

Many epidemiologists, however, disagree.

"In most cases, a scientist would never do this sort of thing," Enstrom said. "It's surprising that they would try to get away with it."

The bottom line is that such "hairsplitting" allowed the EPA to come to a totally different conclusion than it would have using its normal method.

William Reilly

It could now declare that the results of the American studies, when lumped together, were "statistically significant," a term of great importance to the medical community. At a 95% confidence

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U.S. HOUSE OF REPRESENTATIVES
ENERGY AND COMMERCE COMMITTEE
SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT

Statement of Glo Batta Gori, ScD, MPH

JULY 1993

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Source: https://www.industrydocuments.ucsf.edu/docs/gkmm0000

EPA's former research director, Dr. Erich Bretthauer, recently lamented that the agency too often pays more attention to media headlines than to scientific evidence. At the briefing following the press release of the ETS report, Dr. Bretthauer acknowledged that the EPA's $ 26 billion cost estimate for Clean Air Act implementation may prevent fewer than 100 lung cancer cases a year, and perhaps none at all. This is a typical example of over-regulation by EPA without credible scientific support.

Indeed, the Agency's staff disclosed its predisposition with respect to ETS long before the report was even drafted. In 1989 EPA disseminated a so called "fact sheet" asserting that ETS was a known cause of lung cancer and other diseases. The same claim was made in a 1990 draft policy guide aimed at banning smoking in workplaces. In its final report itself, the agency has no hesitation in writing that its analysis was based " on the a priori hypothesis. . .that a positive association exists between exposure to ETS and lung cancer." (1, page 5-2).

The agency and its Science Advisory Board conceded that ETS could be classified as a Group A carcinogen only by disregarding the agency's guidelines for carcinogen assessment – guidelines that are carefully worded according to firmly held scientific principles. In a telling statement, the SAB panel reviewing the ETS risk assessment declared: "If the guidelines for Carcinogen Risk Assessment can be used to cast doubt on a finding that inhalation of tobacco smoke by humans causes an increased risk of lung cancer, the situation suggests a need to revise the guidelines." (SAB report, page 28).

A first requirement of EPA's guidelines – and also an intuitively correct one – is that the substance considered be positively identified. However, what is EPA dealing

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statistical "confidence interval" from the standard 5% margin usually posted -- and employed in early drafts of the EPA report -- to a 10% margin. Naturally, as if by magic the results became statistically significant. Yet, what any self respecting scientist would perceive here is not confidence intervals, but rather a confidence game.

There is more. Two new and large US studies published prior to the release of the ETS report would have made the pooled result statistically not significant -- even under the relaxed standards adopted by the EPA. The agency simply ignored these studies. It also ignored that 12 out of 14 epidemiologic studies of ETS in workplaces failed to detect any elevation of lung cancer risk.

Some would argue that statistical significance is open to interpretation. Still, in epidemiology the 5% standard is universally prescribed as a minimum requirement. This is especially true for epidemiologic studies of potential low level risks for lung cancer, which are notoriously difficult to conduct and interpret. For instance, there is firm evidence that differences in diet, physical activity, disease experience, socioeconomic status, occupation, and other variables can influence the small reported association between marriage to a smoker and risk of lung cancer. One cannot look at ETS alone, as the agency has done. It is as if police came upon a disturbance involving several people, but arrested only one because he "looked" suspicious.

To confirm EPA's fixation on ETS, consider only that the agency dismissed the epidemiologic evidence on electro-magnetic fields, even though 20 of some 40 available studies were statistically significant and reported cancer risks substantially larger than those attributed to ETS.

Thus, EPA's claim that ETS causes 3000 lung cancers a year is a political figment of imagination supported by unwarranted assumptions, selective use of data, artful

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be allowed to act arbitrarily. At the very least, it should be required to obey generally accepted norms of scientific evidence and conduct: norms that are independently justified by their transparent and rational fairness, and their timeless ethical values. The EPA report on ETS flies in the face of the standards of conduct that scientists are required to observe. By any fair measure, the report lays open a reprehensible policy of abuse.

Mr Chairman, that concludes my statement. I will be happy to answer your questions.

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2. Gori, G.B., Mantel, N., Mainstream and environmental tobacco smoke. Regul Toxicol Pharmacol 14:88-105, 1991.

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4. According to a recent review by the World Health Organization, tar is where most of the cancer causing elements of smoke are supposedly found (3, p.195). The EPA states that the risk of lung cancer is directly proportional to the dose (1, page 6-9). Data in the EPA-ETS report lead to the immediate conclusion that the tar dose difference between ETS exposure and actual cigarette smoking is between ten-thousand and hundred-thousand fold (1, table 3-6; 2).

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THE EPA ETS RISK ASSESSMENT:
IMPLICATIONS FOR THE WORKPLACE AND SOCIAL SETTINGS

Following release of the ETS risk assessment, public officials and anti-smoking organizations have claimed that the report provides support for -- and in fact necessitates -- severe restrictions on smoking in workplaces, restaurants and other public areas. In fact, the risk assessment does not even consider data relating to ETS exposures in these settings, and therefore has very little relevance to the public smoking debate.

- The EPA ETS risk assessment is based solely on studies of nonsmokers married to smokers, and therefore presumably exposed to ETS at home.

Workplace Exposure

- The risk assessment provides no analysis at all of exposures occurring in the workplace, although 14 epidemiologic studies addressing this issue -- including many from the U.S. -- have been published in the scientific literature.

- This research provides no support for the suggestion that smoking should be banned. In fact, of 14 studies conducted specifically on workplace exposure, 12 report no statistically significant increase in risk.

Restaurant Exposure

- No epidemiologic studies have been conducted on ETS exposure specifically in restaurants, so claims that the ETS risk assessment supports restaurant smoking restrictions or bans are totally unsupportable.

- A number of studies have attempted to quantify exposure to ETS in restaurants, and most have reported extremely low exposures. One study estimates that a restaurant employee would require nearly 200 hours of continuous exposure to be exposed to the nicotine equivalent of a single cigarette.

- Restaurant patrons and employees would be exposed to many of the constituents of ETS regardless of restaurant smoking policies, since cooking equipment and processes generate the same products of combustion. Claims that ETS generates all or even most of the indoor air constituents found in restaurants are demonstrably wrong.

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Extinguishing Claims From Passive Smokers

BY JOSEPH F. MANGANI

The hazards of tobacco smoke are in the news again, but with a new twist that should make underwriters sit up and take notice. In response to cigarette manufacturers' remarkable success in defending product liability claims by smokers, antismoking activists have taken a new approach: suits by nonsmokers allegedly injured by other people's cigarette smoke. When these suits come to trial, the insurance industry will discover whether juries are more sympathetic to nonsmokers than they have been to smokers, who are consistently found to have voluntarily assumed the risks inherent in tobacco use.

On January 7, the U.S. Environmental Protection Agency released a report classifying environmental tobacco smoke as a Group A, or known, human carcinogen. The EPA report also estimated that secondhand tobacco smoke annually causes the deaths of 3,000 adult nonsmokers due to lung cancer, as many as 300,000 lower-respiratory-tract infections among children under 18 months old, and increases the frequency and severity of symptoms in up to 1 million asthmatic children. The report identifies secondhand smoke as a causal factor in middle-ear infections, upper-respiratory-tract infections and reduced lung function in infants, and as a risk factor for new cases of childhood asthma.

JOSEPH F. MANGANI, CPCU, is editor of Best's Underwriting Newsletter.

EVEN MORE LITIGATION

The report's findings probably will generate calls for new state laws restricting smoking in public places and may prompt the Occupational Safety and Health Administration to develop a standard on smoking in the workplace. The report also provides additional ammunition to nonsmoking plaintiffs who claim to suffer from lung cancer induced by secondhand smoke. Plaintiffs' attorneys already have indicated that litigation will expand beyond tobacco manufacturers to employers and businesses that permit smoking on their premises. If such lawsuits materialize, the defense costs borne by general liability and workers' compensation insurers will increase, although substantive damage awards are unlikely.

While the EPA report presents no new data, its primary conclusions are drawn from 30 epidemiologic studies in eight countries of lung cancer among nonsmoking women whose husbands were tobacco users. Although each study reported a higher incidence of lung cancer among exposed women, only six independently found statistically significant differences. None of the 11 U.S. studies reported a statistically significant increase in risk from secondhand smoke. The 17 studies that ranked subjects by estimated exposure level, which is critical to determining a dose-response relationship, all found the incidence of lung cancer rose with increased exposure, and nine of the studies reported a statistically significant difference at the highest exposure level. Only one study attempted to measure actual exposure to secondhand smoke, and none investigated its possible effects on male subjects.

In analyzing the data from previous studies, EPA staff and the

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Science Advisory Board had to contend with several circumstances that can impede the ability of scientific research to identify a statistically significant relationship between secondhand smoke and lung cancer. Detection of carcinogenic responses usually demands high exposure levels generally found only in occupational settings or experimental animals. Spousal smoking does not produce the high level of exposure researchers would prefer, and animal studies have measured only the effects of direct inhalation of mainstream smoke.

Also, because virtually everyone is exposed to a measurable level of secondhand smoke, it is impossible to isolate a truly unexposed group for comparison with exposed subjects. Therefore, researchers must compare groups with different exposure levels. The background exposure, which generally is higher than spousal exposure, also obscures the effects of passive smoking in the experimental group.

To overcome the problems associated with low incremental exposure and significant background exposure, EPA adjusted the results from all the studies downward to allow for misclassification of active and former smokers as never having smoked. Individual results were assessed for the strength of their association with the overall results and, when exposure level data was available, exposure-response trends. Although two-thirds of the research originally reported no statistically significant association, the probability that their independent results would be so consistent is infinitesimal.

The pooled results produced a larger database with a much higher statistical credibility than any single underlying study. Applying a 90% confidence factor, EPA found a statistically significant increase in the incidence of lung cancer among all exposed subjects and across diverse geographical areas.

As expected, tobacco manufacturers quickly attacked EPA, its report and the classification of secondhand smoke as a Group A carcinogen. The Tobacco Institute accused EPA of adjusting science to fit a specific policy goal, discarding generally accepted statistical guidelines, ignoring significant new research and the recommendations of its own expert panel, basing its classification of secondhand smoke on its chemical similarity to mainstream smoke and acting on the report's conclusions before they had been compiled. While many people believe the institute has strained its credibility, some of its criticism stands on a firm foundation and may influence judicial evaluation of expert testimony based on EPA's findings.

The strongest criticism lies in EPA's acceptance of statistical significance at a 90% confidence level. This departs from all past EPA hazard assessments and generally accepted research standards, which demand at least 95% confidence to support conclusions as strong as those drawn by EPA. Adoption of such a significant procedural change on a highly controversial issue may raise serious questions about the validity of their conclusions. However, the Tobacco Institute's insistence on evaluating only the results of individual studies also appears to be misplaced because it would discard a scientifically valid tool for assessing data from diverse sources.

The EPA report indicates that spousal smoking is the only single source of secondhand smoke that makes a material contribution to the incidence of lung cancer.

MORE CRITICISM

The Tobacco Institute further criticizes EPA for omitting a 1992 study funded by the National Cancer Institute that found no statistically significant association between secondhand smoke and adverse health effects. If these findings are added to the database, the statistical significance of the link between passive smoking and lung cancer disappears, the institute claims. But the National Cancer Institute research was published in November, when EPA was finishing its report, and requiring its incorporation into the database is unreasonable. However, any new scientific evaluation supporting the institute's contention would serve to discredit EPA's conclusions and impair their evidentiary value.

While EPA awarded a contract for preparation of a "Workplace Policy Guide" on smoking before finalizing its formal risk assessment, that does not necessarily indicate bias or predetermined policy objectives. Because research begins with gathering, collating and analyzing data, its conclusions often are known before the formal report is drafted, which can take months or even years for government agencies.

At this time, there is little reason for underwriters to expect the classifica-

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tion of secondhand smoke as a Group A carcinogen to have any significant effect on damage awards. Plaintiffs still must bear the burden of proving a causal relationship between exposure to secondhand smoke and their own injuries, a process that is much more difficult than simply attributing the deaths of 3,000 nonsmokers each year to passive smoking. The scientific evidence supporting the risk assessment is the least persuasive EPA has ever accepted and there already are indications that new research may discredit its findings. Also, epidemiologic research is of little value in determining the likely cause of any individual case of lung cancer. In addition, tobacco companies remain the most promising defendants, and they have long since abandoned the search for affordable product liability insurance.

NONEXPERT TESTIMONY

The judiciary also may question the validity of the evidence used to measure the adverse health effects of secondhand smoke. Burned by hundreds of lawsuits and several multimillion-dollar verdicts founded on "scientific" evidence that later was discredited, judges have begun to take a more critical look at expert testimony. A growing number of courts have refused to admit expert testimony that is not based on generally accepted scientific theory and methodology. In departing from its own established standards and those of the scientific community, EPA's classification of secondhand smoke as a Group A carcinogen will be scrutinized carefully.

Businesses that permit smoking on their premises may face claims by customers or employees, but the prevalence of secondhand smoke, the relatively low level of exposure and the questionable scientific evidence linking it to adverse health effects should provide adequate defense. Plaintiffs who are successful in attributing their cancer to passive smoking will face the formidable task of persuading a jury that a single source of exposure is at least the principal cause of their illness. Also, despite pervasive exposure to secondhand smoke in social and occupational settings, the EPA report indicates that spousal smoking is the only single source that makes a material contribution to the incidence of lung cancer. Research on male subjects and occupational exposure to secondhand smoke consistently has failed to find a statistically significant link to lung cancer or any other pathological condition. □

LOSS NOTES

Continental Introduces Farm Fire-Safety Guide

Continental Insurance, New York, distributed the fourth in a series of Farm Safety-Awareness Guides to its farm insurance agents. The guide addresses fire hazards and prevention, loss-control procedures and emergency responses. Previous guides covered farm vehicle safety, all-terrain vehicle safety and pesticide handling. Subsequent farm safety-awareness guides are planned.

CCC Provides Cash Values On Equipment, Vehicles

CCC Information Services, Chicago, introduced a program that provides underwriters with a regionalized cash value and description of insured heavy equipment and commercial vehicles. The regionalized cash value helps underwriters and clients match insurance protection to equipment value and serves as a reference in claims handling. The service also accommodates improvements or repairs to the insured property during the policy period.

IMUA Schedules Seminars On Disasters in Midwest

The Inland Marine Underwriters Association is holding seminars on the potential effect of floods, tornados, hurricanes, hail and earthquakes in the Midwestern states. The seminars will be held May 18 in Chicago and May 19 in Minneapolis and Columbus, Ohio. To register, contact Barbara Spain at (312) 559-9330, Lynda Olson at (612) 893-5968 or Ann Boehmcke at (312) 648-5165.

Lindsey Morden Opens Office in Wichita, Kan.

Lindsey Morden Claims Services, Tyler, Tex., opened an office in Wichita, Kan. The office, located in Suite 1, 8017 East Douglas, is managed by Don Reed, who previously was a multiline adjuster in Lindsey Morden's Amarillo, Tex., and Lawton, Okla., branches. The Wichita office telephone number is (316) 684-4114.

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LETTER TO THE EDITOR

Dear Editor:

In an article in the May 1993 issue of *Corporate Legal Times*, Michael J. Astrue, a former general counsel of the U.S. Department of Health and Human Services, suggested that employers should ban smoking in the workplace to avoid potential liability to non-smoking employees ("EPA Ruling on Secondary Smoke Creates Risk for Employees," pg. 456). Astrue believes that the recent U.S. EPA report classifying environmental tobacco smoke (ETS) as a Group A carcinogen will fuel disability and other claims.

Astrue overestimates the significance of the EPA report, and his discussion of the pertinent case law is wide of the mark. There have been few successful workplace claims based on ETS exposure, and it is unlikely that the EPA report will change this.

The fact that a substance has been given the Group A label does not mean it must be banned. Group A substances are common. They include benzene, which is emitted from barbecue grills, gas-fired stoves and drinking water; and nickel, which is used in kitchen utensils and tableware.

The U.S. Occupational Safety and Health Administration typically does not ban Group A substances in workplaces. OSHA, not EPA, has regulatory authority over workplace smoking, and OSHA currently is considering whether ETS presents an occupational risk. The vast majority of workplace smoking studies (which EPA ignored in its report, but which OSHA must consider) report no statistically significant increase in overall lung cancer risk. EPA's conclusion that ETS is capable of causing cancer in humans has drawn, and continues to draw, criticism.

Astrue suggests that the Americans with Disabilities Act requires a complete ban on smoking in the workplace. In promulgating rules implementing the ADA, however, the U.S. Equal Employment Opportunity Commission made clear that sensitivity to environmental agents such as ETS does not automatically constitute a "disability." The U.S. Court of Appeals for the Sixth Circuit specifically has held (in *Pletten v. Merit Systems Protection Board*, 1990 U.S. App. LEXIS 11900 (6th Cir. 1990)) that providing an individual with a "totally smoke-free environment" goes beyond the government's obligation to provide "reasonable accommodation" under the parallel provision of the Rehabilitation Act of 1973.

Astrue also predicts that state workers' compensation suits based on workplace exposure to ETS increasingly are likely to succeed. But the very few cases in which non-smoking employees have been awarded workers' compensation involved an unusual combination of two elements: the non-smoking employee was found to be "hypersensitive" to ETS or to suffer from a pre-existing medical condition found to be aggravated by ETS, and the employer had forced the non-smoking employee to share his or her immediate workspace on a sustained basis with smoking employees. It is evident as well in these cases that the workspace was inadequately ventilated.

The decided cases make clear that employers need not ban smoking to minimize the risk of claims by non-smoking employees. The key is a policy that provides employees with an adequately ventilated working environment and does not force objecting nonsmokers to share their immediate workspace on a sustained basis with smoking colleagues.

John C. Fox
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Smoking in the Workplace: Accommodating Diversity*

By John C. Fox and Bernadette M. Davison

Mr. Fox is a partner in, and Ms. Davison is associated with, the law firm of Pillsbury, Madison & Sutro in San Francisco, California.**

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Historically, individuals who smoked typically felt free to do so when and where they pleased. Indeed, smoking in public places, including places of work, was generally unrestricted. Today, however, the interests of smokers and nonsmokers often compete on the job. This is especially true in workplaces where employees work side-by-side for long periods of time. While some employees adamantly seek to preserve their "right" to smoke on the job, other nonsmoking employees are pushing for a "right" to a smoke-free work environment. And, while smoking disputes are still generally resolved informally by management, now legislatures, courts, and unions have become embroiled in the controversy.

In this article, the authors present an overview of workplace smoking issues by surveying relevant case law, analyzing state and local legislation, and addressing the prominent role of unions regarding smoking in the workplace. In addition, the authors offer practical suggestions to employers about how to accommodate the competing interests of both smokers and nonsmokers. In doing so, the authors hope to assist employers in resolving workplace smoking issues.

Eighty-eight percent of all employers in the United States permit smoking in the workplace.[1] Of those employers that permit smoking, approximately one-half currently have no formal smoking policy.[2] Twelve percent of major employers in the United States ban smoking on the job. The vast majority of employers permit smoking somewhere on company premises. Fifty-one percent prohibit smoking in open work areas and shared work spaces.[3] Of the employers that ban smoking in the workplace, many appear to do so around food preparation stations or where employees work near combustible materials. For example, gasoline refineries and chemical processing companies ban smoking almost uniformly due to the severe safety considerations attendant to those workplaces. Similarly, product contamination concerns led the Campbell Soup Company to ban smoking in the workplace beginning in approximately 1896.

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** The firm of Pillsbury, Madison & Sutro provides legal services to The Tobacco Institute, a trade association representing the interests of American cigarette manufacturers. The views expressed herein are those of the authors and do not necessarily reflect the views of The Tobacco Institute or Pillsbury, Madison & Sutro.

[1] BNA, "Where There's Smoke: Problems and Policies Concerning Smoking in the Workplace, A Special Report" 20 (2d ed. 1987) (hereinafter BNA, Special Report).

[2] According to one survey of 1,100 employers, 63.8 percent have no formal smoking policy. A more recent survey of 623 employers indicated that 43 percent have no such policy. See infra note 73 and accompanying text.

[3] BNA Special Report, supra note 1, at 20.

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Judicial Response

In general, the courts have been quite hostile to the claims of nonsmokers seeking a legal right to a smoke-free work environment. That same conclusion also appears to be emerging in the new wave of "smokers' rights" cases. The consensus of the courts appears to be that, absent any legislative limitation on management's discretion, employers need to accommodate the competing interests of both smoking and nonsmoking employees. For example, management must accommodate "handicapped" employees who are found to be medically "hypersensitive" to environmental tobacco smoke.[8] On the other hand, unionized workers may have a right to smoke unless and until management has bargained in good faith to limit smoking in the workplace. At the same time, management must comply with any state statutes or local ordinances that may address smoking in the workplace.

Inevitably, employers find themselves positioned between the competing interests of smokers and nonsmokers alike. In this situation, employers are well-advised to promptly and effectively accommodate these competing interests so as to avoid disruptive battles between employees. In some situations, employers may consider voluntarily formulating a reasonable smoking policy to assist them toward this end.

Workplace smoking issues have been litigated in the courts in a variety of contexts. Beginning in 1976, nonsmokers filed the first of a series of "test cases" seeking the legal right to a smoke-free work environment.[9] With a few limited exceptions, the courts have been hostile to the claims of healthy nonsmokers seeking a legal right to a smoke-free work environment. Instead, the general response of the courts has been that this is an issue best left to management discretion or the legislative process.[10]

Constitutional Claims

The courts have summarily rejected the notion that employees or members of the public have a constitutional right to an environment free of tobacco smoke. In the leading decision, *Gasper v. Louisiana Stadium and Exposition District*,[11] a group of nonsmokers sought to prohibit smoking during sports and other public events at the Louisiana Superdome. The plaintiffs claimed that their exposure to tobacco smoke in the Superdome infringed upon their rights guaranteed by the U.S. Constitution. Specifically, the plaintiffs in *Gasper* alleged that exposure to tobacco smoke at the Superdome infringed upon their First Amendment right to receive ideas; deprived them of life, liberty, and property without due process in violation of the Fifth and Fourteenth Amendments; breached their fundamental privacy rights guaranteed by the Ninth Amendment. The court rejected each of the plaintiffs' constitutional arguments and stated that to hold that the Constitution prohibits smoking would be to create an unprecedented avenue "through which an individual could attempt to regulate the social habits of his neighbor."

(Footnote Continued)

Indoor and Ambient Air Quality Conference, *Imperial College* (London, England, June 13-15, 1988) [hereinafter Proceedings].

See also Comment, *Judicial and Legislative Control of the Tobacco Industry: Toward a Smoke-Free Society?* 56 U. Cin.L. Rev. 317 (1987); and Crist & Majoras, *The "New" Wave In Smoking and Health Litigation—Is Anything Really So New?* 54 Tenn.L. Rev. 551 (1987).

[8] See *Parodi v. Merit Sys. Protection Bd.*, 702 F.2d 743, 749-51 (9th Cir. 1982); see also infra note 27 and accompanying text.

[9] See *Shimp v. New Jersey Bell Tele.*, 145 N.J. Super. 516, 368 A.2d 408 (1976).

[10] See, e.g., *Federal Employees for Nonsmokers' Rights v. United States*, 446 F.Supp. 181, 185 (D.D.C. 1978), aff'd 598 F.2d 310 (D.C. Cir. 1979), cert. denied, 444 U.S. 926; *Gasper v. Louisiana Stadium & Exposition Dist.*, 418 F.Supp. 716, 722 (E.D. La. 1976); *McCarthy v. Department of Social and Health Servs.*, 110 Wash. 2d 812, 826, 759 P.2d 351, 358 (1988).

[11] 418 F. Supp. 716 (E.D. La. 1976), aff'd 577 F.2d 897 (5th Cir. 1978), cert. denied, 439 U.S. 1073 (1979).

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Statutory Claims

Nonsmokers have relied upon numerous statutes attempting to limit smoking in the workplace or, alternatively, to obtain financial benefits if they believe they cannot continue working in the presence of tobacco smoke. These statutory bases include federal and state handicap laws, disability statutes, and workers' compensation laws.[19]

Despite these attempts, the courts have generally refused to restrict workplace smoking. Some courts, however, have held that employees claiming severe adverse reactions to tobacco smoke are "handicapped" or "disabled" or may be able to recover workers' compensation benefits.

In *Vickers v. Veterans Administration,*[20] the court found that an employee was "handicapped" within the meaning of Section 504 of the Federal Rehabilitation Act of 1973[21] when it found him to be "hypersensitive"[22] to tobacco smoke and physically unable to perform his job in the presence of environmental tobacco smoke.[23] In *GASP v. Mecklenburg County,*[24] however, the court rejected similar claims, cautioning that the term "handicap" was *not* intended to include all persons who claim to suffer from a pulmonary problem, however minor, or those who are simply irritated by tobacco smoke.

In the workers' compensation context, a California court has held that a nurse who left her job because of "allergic" reactions to tobacco smoke was eligible for unemployment compensation until she could find alternative employment in a smoke-free environment.[25] A Louisiana court has denied unemployment benefits under similar circumstances because it found that the employee's preexisting allergy, which was not aggravated by her employment, did not constitute "good cause" for her resignation.[26]

In *Parodi v. Merit Systems Protection Board,* a federal employee who claimed to

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[19] The Occupational Safety and Health Act (OSHA), 29 U.S.C. §§ 651-678 (1982) currently provides no remedy for nonsmokers seeking a smoke-free work environment. Tobacco smoke is not listed by OSHA as a "toxic and hazardous substance." See 29 C.F.R. § 1910.1000-1910.1500 (1988). Indeed, in 1987 OSHA denied a citizen petition requesting OSHA to classify tobacco smoke as a potential occupational carcinogen and develop a standard for "tobacco smoke." BNA, Daily Report for Executives at A-24 (Mar. 2, 1987). In addition, OSHA administrators have consistently refused to accept complaints based solely on workplace smoking and, thus, apparently do not perceive that environmental tobacco smoke constitutes a violation of an employer's statutory duty to provide a "healthful" working environment. Moreover, OSHA provides no private right of action for employees who seek to restrict workplace smoking. See *Federal Employees for Nonsmokers Rights v. United States,* cited at note 10; *Barrera v. E. I. du Pont de Nemours,* 653 F.2d 915, 920 (5th Cir. 1981).

[20] 549 F. Supp. 85 (W.D. Wash. 1982).

[21] 29 U.S.C. §§ 701-796i (1982). The Rehabilitation Act imposes affirmative action and nondiscrimination obligations upon a limited group of employers: federal agencies, federal contractors, and recipients of federal assistance.

[22] The *Vickers* court used the terms "hypersensitivity" and "unusually sensitive" interchangeably. See 549 F.Supp. at 87. In medical terms, "hypersensitivity" is defined as "a state of altered reactivity in which the body reacts with an exaggerated response to a foreign agent." Dorland's Illustrated Medical Dictionary 635 (25th ed. 1981).

This term must not be confused with "allergy" or "allergic reaction." To date, no specific antigens have been identified in *tobacco smoke,* and when individuals claim to be "allergic" to smoke, at best, they can be said to suffer from non-specific responses to smoke exposure. See Lehrer, *Tobacco Smoke Sensitivity: A Result of Allergy?* Annals of Allergy 56, May 1986, at 1-10.

[23] The *Vickers* court did not award any injunctive or monetary relief, however, because it found that (1) the employer did not discriminate against plaintiff by reason of his handicap; (2) the employer made reasonable efforts to accommodate plaintiff. 549 F. Supp. at 87-89. For a thorough analysis of the *Vickers* decision, see Comment, *Limited Relief for Federal Employees Hypersensitive to Tobacco Smoke: Federal Employer Who'd Rather Fight May Have to Switch,* 59 Wash.L. Rev. 305, 312-22 (1984). See also *Department of Fair Employment and Hous. v. Fresno County,* FEHC Dec. No. 81-82 (C8-0009 ph) (1984) (employee allergic to tobacco smoke found to be "handicapped" under California Fair Employment and Housing Act).

[24] 42 N.C. App. 225, 256 S.E.2d 477 (1979).

[25] *Alexander v. California Unemployment Ins. Appeals Bd.,* 104 Cal. App. 3d 97, 163 Cal. Rptr. 411 (1980). See also *McCrocklin v. Employment Dev. Dept.,* 156 Cal. App. 3d 1067, 205 Cal. Rptr. 156 (1984) (employee's "good-faith fear" that smoke-filled room was harmful to his health found "reasonable" and employee entitled to unemployment benefits).

[26] *Billman v. Sumrall,* 464 So. 2d 382 (La. App. 1985). But see *Lapham v. Pennsylvania Unemployment Compensation Bd. of Review,* 103 Pa. Commw. 144, 519 A.2d 1101 (1987) (bronchitis sufferer entitled to collect unemployment benefits where proffered physical relocation was deemed not a "reasonable accommodation"); *McCrocklin,* 156 Cal. App. 3d 1067, 205 Cal. Rptr. 156.

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hazardous or flammable materials, may constitute a "business necessity."[33] Unless required by statute or ordinance, however, it is unlikely that courts would find that the preferences of co-employees or customers rise to the level of a business necessity.[34] Even so, the court could still find a Title VII violation if the employee proves that there are other alternatives that accomplish the same business purpose, yet have less impact on blacks.[35]

Accordingly, employers need to examine carefully current or proposed workplace smoking restrictions to ensure that they do not discriminate against protected groups. If they do, the employer must be prepared to establish that the smoking policy adopted is justified by legitimate business purposes and is the least drastic means of accomplishing the employer's goals.[36]

Common Law Claims

An employer's general common law duty to provide a reasonably safe working environment for its employees has been codified by federal and state occupational safety and health (OSHA) laws.[37] In an attempt to restrict workplace smoking, employees have filed several lawsuits claiming that such smoking violates this general common law duty. However, only one lower court decision, in New Jersey, *Shimp v. New Jersey Bell Telephone*,[38] has found an employer permitting smoking in the workplace to have violated this duty. The remainder of the courts confronted with this issue have declined to find the duty violated and have refused to restrict workplace smoking. Thus, there is currently little, if any, authority for imposing a common law obligation upon employers to restrict smoking in the workplace.

In *Shimp*, a secretary who claimed to suffer from a severe "allergic" reaction to tobacco smoke sought an injunction to prevent other employees from smoking in her work area. Plaintiff submitted medical opinions in support of her request for an injunction. The employer, on the other hand, failed to put forth any evidence to refute the plaintiff's claims. Not surprisingly, the New Jersey Superior Court found that the employer had a common law duty to provide safe working conditions. Accordingly, it directed the

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[33] A prima facie case is sufficient to prove a Title VII violation, unless contradicted or overcome by other evidence. *McDonnell Douglas Corp. v. Green*, 411 U.S. 792 (1973).

To prove a business necessity, an employer may show that the policy or practice has a "manifest relationship" to performance of the job in question (i.e., that it is a "job related criterion"). Alternatively, the employer may seek to prove that the policy or practice in question is necessary to the safe and efficient operation of the business. "[A] discriminatory employment practice must be shown to be necessary to safe and efficient job performance to survive a Title VII challenge." *Dothard v. Rawlinson*, 433 U.S. 321, 332 n.14 (1977).

[34] See, e.g., *Moore v. Inmont Corp.*, 608 F. Supp. 919, 927 (W.D.N.C. 1985)

[35] See *Rucker v. Higher Educ. Aids Bd.*, 669 F.2d 1179, 1181 (7th Cir. 1982) (employer is forbidden by Title VII to refuse to hire someone on racial grounds because his customers or clientele do not like his race); *Dias v. Pan Am World Airways*, 442 F.2d 385 (5th Cir.), cert. denied, 404 U.S. 940 (1971) (Pan Am violated Title VII when it banned employment of male flight attendants despite passenger preferences for female flight attendants); *Bing v. Roadway Exter.*, 444 F.2d 687 (5th Cir. 1971) (invalidating a motor freight company's rule that an employee who desired to transfer to another job must resign his present position and thereby forfeit accrued employment rights. Finding the rule to have an adverse impact on blacks, the court rejected the company's argument that the rule was "necessitated" by the prospect of employee unhappiness with the demise of the rule). Accord *Jones v. Lee Way Motor Freight*, 431 F.2d 245 (10th Cir. 1970), cert. denied, 401 U.S. 954 (1971).

[36] See *Dothard v. Rawlinson*, cited at note 33. If an employer meets the burden of showing that its tests or selection devices are job-related, the burden then shifts to the complaining party to show that other less discriminatory selection devices would also serve the employer's legitimate interests. See also *Albemarle Paper Co. v. Moody*, 422 U.S. 405, 425 (1975).

[37] See 29 U.S.C. §§651-678 (1982) (Federal OSHA). Section 654(a) sets forth the so-called "general duty" clause, which requires that an employer "shall furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or likely to cause death or serious physical harm to his employees." See also supra note 19.

See also Cal. Labor Code §§6300-6711 (Deering Supp. 1988) (Cal-OSHA). Section 6400 provides that "[e]very employer shall furnish employment and a place of employment which are safe and healthful for the employees therein."

[38] Cited at note 9.

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ees who protest corporate policies permitting smoking. In *Hentzel v. Singer Co.*,[43] a California court held that an employee could state a common law retaliatory dismissal claim after being terminated for protesting hazardous working conditions. The court did so without addressing whether the alleged hazard (environmental tobacco smoke) was, in fact, hazardous.

Overall, the courts have been reluctant to find any common law basis for restricting workplace smoking in the absence of sufficient proof that environmental tobacco smoke causes significant medical harm to nonsmokers.[44] With the exception of the now dated and criticized 1976 *Shimp* decision, the courts have declined to expand an employer's common law duty to provide a safe working environment to encompass a smoke-free working environment.

In 1986, in *Bernard v. Cameron & Colby Co.*, a Massachusetts court rejected a nonsmoker's claim against her employer based on breach of contract and intentional and negligent infliction of emotional distress.[45] But, in *McCarthy v. Department of Social and Health Servs.*, the Washington Supreme Court recently held that an employee who allegedly developed lung disease as a result of exposure to tobacco smoke in the workplace was not preempted by workers' compensation laws from stating a cause of action against her former employer for negligence.[46] This finding is inconsistent with existing labor law precedents. While four justices opined in dicta that employers have a common law duty to provide a smoke-free work environment, that conclusion was specifically rejected by a majority of the court.[47] Indeed, several courts that have addressed the issue to date have recognized the need to consider the interests of both smokers and nonsmokers.[48]

Workplace Smoking Legislation

In addition to analyzing case law, the workplace smoking issue demands a careful review of relevant state and local legislation.[49] Thirteen states to date have enacted legislation specifically regulating smoking in private workplaces. These are: (1) Connecticut; (2) Florida; (3) Iowa; (4) Maine; (5) Minnesota; (6) Montana; (7) Nebraska; (8) New Hampshire; (9) New

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[43] 138 Cal. App. 3d 290, 188 Cal. Rptr. 159 (1982).

[44] In fact, no link has been shown between ETS and chronic adverse health effects. Both the Surgeon General and the National Academy of Sciences found that available studies preclude any firm conclusion about the relationship between exposure to ETS and cardiovascular disease and that further studies are needed to determine whether any real link exists. See, e.g., Surgeon General's Report, cited at note 7, at 14; NAS Report, cited at note 12, at 11. In addition, the Surgeon General's report concluded that "a previously healthy individual would not develop chronic lung disease solely on the basis of involuntary tobacco smoke exposure in adult life." Surgeon General's Report, supra note 12, at 62. Finally, both the Surgeon General and the National Academy of Sciences reports emphasize critical limitations on their finding of a possible connection between exposure to ETS and lung cancer. Upon reviewing the same evidence considered by the NAS and the Surgeon General, the International Agency for Research on Cancer of the World Health Organization concluded, in 1986, that the available evidence is equally consistent with the finding of an increase in risk or absence of risk. IARC Monograph, cited at note 12, at 308. A number of other studies published since 1986 also contradict the limited findings of the Surgeon General and NAS reports with respect to the purported relationship between ETS and lung cancer. See, e.g., Proceedings, supra note 12, at 242-50, 252-58.

[45] *Bernard v. Cameron & Colby Co.*, 397 Mass. 320, 491 N.E.2d 604 (1986).

[46] Cited at note 10.

[47] *Id.* (Brachtenbach, J., dissenting). In a statement issued by the Washington State Attorney General's office, a spokesperson for the attorney general said that the dicta of the three justices in *McCarthy* did not establish binding law on the issue of an employer's duty to provide a "reasonably safe" workplace. 26 Governmental Employment Relations Report 1172 (Aug. 1988). A trial on the merits in *McCarthy* is scheduled for October, 1989.

[48] See *Shimp v. New Jersey Bell Tel.*, cited at note 9; *Gordon v. Raven Sys. & Research*, 462 A.2d 10, 15 (D.C. App. 1983); *McCarthy*, cited at note 10.

[49] There is no federal legislation regulating smoking in private workplaces. The United States government has, however, adopted smoking restrictions covering the 6,800 buildings controlled by the General Services Administration. These restrictions apply to approximately 890,000 federal employees. See 41 C.F.R. Part 101-20.105-3. In addition, the Federal Labor Relations Authority has recently restricted the ability of several federal agencies to change smoking policy without first negotiating with bargaining units. *Treasury Employees Union Chapter 250*, 33 FLRA No. 8, 61-74 (Before Calhoun and McKee) (Oct. 13, 1988), Nos. 0-NG-1524, 0-NG-1536 and 0-NG-1545.

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limit management's discretion. These laws generally dictate which portions of the workplace must be designated as no-smoking areas. Also, these laws usually specify the percentage of space in employee cafeterias, lunchrooms, and lounges that must be reserved for nonsmokers. In some instances, these most intrusive laws give nonsmoking employees superior rights over smokers. For example, the local ordinance in Palo Alto, California, provides that "[i]n any dispute arising under the policy, the rights of the nonsmoker shall be given precedence."[55]

Objections to Legislation

The primary and most obvious objection to legislative enforcement of workplace smoking is that it usurps the ability of employers to deal individually with employee concerns as they arise. Legislation does not add to management's bevy of rights; rather, such legislation takes away the considerable flexibility employers have historically enjoyed in this area. In addition, there are numerous other potential objections to legislation covering workplace smoking.

First, smoking laws, like workplace smoking policies, can be difficult to enforce. Regardless of whether this responsibility is placed on the employer or some governmental body, such as a law enforcement agency or local health department, limited resources and personnel make rigorous enforcement of workplace smoking laws unlikely. Second, because workplace smoking is generally considered to be a *mandatory* subject of bargaining, legislative restrictions may create conflicts between employers and unions. Third, restrictions imposed by smoking legislation may interfere with worker efficiency. For example, where compliance with the law requires employers to rearrange work areas or segregate smoking and nonsmoking employees, an employer's operations may be disrupted and productivity decreased.[56] Fourth, smoking laws that give nonsmokers unlimited power to dictate the company policy for all workers are likely to be perceived as unfair by others, especially employees who smoke. For instance, a local ordinance in San Francisco allows even one employee to veto an employer's smoking policy in that employee's "office workplace."[57] These types of policies will undoubtedly create resentment among some employees and foster the perception that employers unfairly favor nonsmokers.[58] Fifth, where legislation requires employers to physically separate smokers and nonsmokers, employers may experience a loss of managerial freedom. Finally, some state or local laws regulating smoking in the workplace are likely to be challenged on constitutional or other grounds, and may thus embroil employers in resulting litigation.[59]

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[55] Palo Alto Municipal Code, ch. 9.14, effective Feb. 1, 1984.

[56] According to one study, of those employers polled who have implemented smoking restrictions, seven percent responded that their policies have had a notable effect on company costs. Eight percent indicated that employee productivity increased, while three percent reported that their restrictions had a detrimental effect on employee productivity. BNA, Special Report, supra note 1, at 22-23. For an economist's view of the "social costs" of smoking, including lost production, workplace efficiency, and absenteeism, see R. Tollison & R. Wagner, Smoking and the State ch. 3 (1988).

[57] San Francisco Municipal Health Code, Smoking Pollution Control Ordinance No. 298-83 (Proposition P), effective Mar. 1, 1984.

[58] Thus far, employee sentiments about smoking policies have been mixed. Overall, 42 percent of recent survey respondents said the smokers think their policy is "about right," while 33 percent indicated the rules were too restrictive; 53 percent of firms with policies said that nonsmokers were satisfied, while 33 percent said nonsmokers wanted tougher restrictions. BNA, Special Report, supra note 1, at 23.

Press accounts of employee sentiment are decidedly mixed as well. See *Do You Smoke? Drink? If So, Some Employers Say, You May as Well Stay Home*, Business First-Columbus, vol. 3, no. 36, § 2, at 3; *The Company Is Watching You Everywhere*, N.Y. Times, Feb. 15, 1987, § 4, at 21, col. 2, (Editorial Desk); *Some Workers Upset by Company Smoking Ban*, AP, Jan. 21, 1987; *Bans, Red Ink: Smoking: A Burning Issue*, L.A. Times, Nov. 21, 1985, § 1, at 1, col. 1, (Metro Desk); *Where There's Smoke, There's Ire: After Years on the Defensive, Smokers Fight Back*, L.A. Times, Jan. 14, 1988, § 4, at 1, col. 1.

[59] The primary challenge is that smoking laws are often too vague to set definite standards of compliance for employers. Indeed, several smoking ordinances have already

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a recognized right or privilege of employment.

This issue was discussed in *In re Parker Pen U.S.A.*[65] In this case, the employer, who had permitted on-the-job smoking for over twenty years, unilaterally abolished employee smoking rights that were guaranteed under the collective bargaining agreement. The employer allegedly did so for health reasons after receiving the Surgeon General's 1986 report on involuntary smoking. In resolving an employee grievance, the arbitrator held that "both parties have an interest in addressing the profound issue raised by the employer concerning the safety of the workplace." Accordingly, the arbitrator invalidated the employer's smoking ban until any changes could be bargained over during upcoming negotiations.

Even where the employer is required to impose smoking restrictions pursuant to state statute or local ordinance, it should bargain over all discretionary aspects of the rule. There are no "smoking policy" cases directly on this point. The institution of a smoking policy would constitute a "term and condition" of employment and, therefore, be a mandatory subject of bargaining. Nevertheless, neither union nor management may require the other to agree to provisions that are unlawful or prohibited.[66] Thus, proposed or existing provisions that directly conflict with legislation automatically become illegal or unenforceable.[67] Legislation that provides employers with discretion, however, such as that which simply requires employers to "adopt" a smoking policy, would not be affected. That is, the particular discretionary aspects of the policy would still be a mandatory subject of bargaining. In practice, bargaining will be routinely required because most workplace smoking laws leave a considerable amount of discretion to employers.[68]

Even if the unilateral implementation of a smoking policy does not violate the NLRA, it may nonetheless violate the collective bargaining agreement. Arbitral decisions have consistently stated that to be valid, an employer rule must be reasonable under the circumstances and nondiscriminatory in application.[69] Arbitrators have struck down employer smoking policies that fail to meet this standard.

In *Union Sanitary District*, the arbitrator found that the employer could not unilaterally prohibit employees from smoking in their offices. Specifically, the arbitrator found that the absolute prohibition was arbitrary because there was no adequate basis for the rule. Although the employer stated it wanted to protect nonsmoking employees, the evidence showed there were only two bargaining unit members in the building who smoked. Furthermore, for six hours a day, they were not in their offices but were out in the field, and no one complained about the smoking. Moreover, the California Indoor Clean Air Act of 1976, which the employer cited to justify its ban, did not require a ban on smoking. Rather, that Act contemplates a relatively flexible regulation of smoking which recognizes the rights of both smokers and nonsmokers.[70]

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[65] 90 Lab. Arb. (BNA) 489 (1987) (Fleischli, Arb.).

[66] *Meat Cutters Local 421*, 81 N.L.R.B. 1052 (1949); *Borg-Warner v. NLRB*, 356 U.S. 342, 34 LC ¶ 71,492 (1958).

[67] *Hughes Tool Co.*, 147 N.L.R.B. 1573 (1964); *Savannah Printing Specialties & Paper Prod. Local 604 v. Union Camp Co.*, 50 F. Supp. 632, 70 LC ¶ 13,542 (S.D. Ga. 1972).

[68] For example, the New Hampshire law, cited at supra text accompanying note 54, merely directs the employer to adopt a smoking policy. All of the specifics are left to the discretion of each individual employer.

[69] See *United Tele. Co. of Florida*, 78 Lab. Arb. (BNA) 865 (1982)(designation of no-smoking table in cafeteria upheld as reasonable in light of company's and union's interests in maintaining a healthy work environment and minimizing expenses and potential liability); *H-N Advertising & Display Co.*, 88 Lab. Arb. (BNA) 329 (1986), 88 Lab. Arb. (BNA) 1311 (1987) (rule banning smoking in area of plant where combustibles are stored was reasonable and nondiscriminatory where worker safety was primary reason for expanding rule, and implementation of measures to improve safety is normally management prerogative). See also supra note 64.

[70] *Union Sanitary District*, cited at note 64. CAL. HEALTH & SAFETY CODE § 25940-25947 (Deering 1988). See also *Schien Body & Equip. Corp.*, cited at note 64

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Drafting a Smoking Policy

In jurisdictions where workplace smoking is governed by a state statute or local ordinance, employers must conform their policies and practices to the law. In some circumstances, this may require employers to adopt a formal smoking policy. In the vast majority of jurisdictions, however, employers are still free to decide whether a smoking policy is necessary or appropriate. In doing so, employers may want to evaluate whether there is a predicate for action. In this regard, they may find it useful to survey their employees to see if there is a consensus of opinion. Management may also want to consult its labor unions, if any.

Should a company decide that a formal written policy is necessary, the specifics of the policy will naturally depend upon the individual aspects of the workplace. Because of local differences, particularly in those companies with decentralized decision-making, some companies have developed a smoking policy applicable to only some divisions, offices, or plants. Other employers have adopted a smoking policy in response to a specific problem or where they are governed by a particular local ordinance. In addition, companies tend to vary their smoking policies depending upon the degree of specificity desired. A less specific smoking policy aimed at promoting cooperation and consideration might, for example, state:

"It is our policy to make every reasonable effort to accommodate all employees within the constraints imposed by our physical structure and financial resources. It is our firm conviction that the wishes of smokers and nonsmokers can best be resolved through cooperation, dialogue, and common courtesy. Should a dispute or concern arise, management and employees should work together to seek a reasonable resolution consistent with this policy." A nonspecific policy such as this will increase flexibility and allow management to resolve individual disputes on a case-by-case basis.

In contrast, some employers may opt for a smoking policy with a greater degree of specificity. For instance, the employer may want to designate particular smoking or nonsmoking areas or workstations. The specific locations covered may include: private offices, hallways, conference rooms, lunch rooms, restrooms, and auditoriums. If enforced in an arbitrary or discriminatory manner, a smoking policy may subject an employer to potential liability. Indeed, inequitable enforcement could foster employee discontent and possibly support claims premised on breach of contract or tort claims against employers or individual supervisors.[74]

Smoking bans, while rare, pose more serious problems.[75] This is especially true if they proscribe off-duty behavior. In addition to employee morale problems, these bans are likely to give rise to a morass of legal claims.[76] For these reasons, employers should be extremely cautious before considering a total ban on workplace smoking.

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[74] See *Carroll v. Tennessee Valley Auth.*, 697 F.Supp. 508 (D.D.C. 1988) (public employer not shielded from potential tort liability under "official immunity" doctrine, because supervisor who failed to enforce smoking policy acted outside course and scope of his employment). In *Carroll*, the plaintiff claimed that she had developed lung disease allegedly from exposure to environmental tobacco smoke on the job. In addition, she alleged that her supervisors took reprisals against her by giving her poor performance evaluations, assigning her demeaning work, and questioning the seriousness of her health claims. On November 1, 1988, this case was settled for an undisclosed sum of money.

[75] The vast majority of employers with smoking policies do not ban smoking entirely. As noted above, those who do typically do so due to product (food) contamination concerns or because flammable materials are produced or stored in the workplace. And few (five percent) give hiring preference to nonsmoking job applicants. BNA, Special Report, supra note 1, at 17, 22. One notable exception pertains to police and fire departments, which are faced with unique workers' compensation issues. See supra notes 15-18 and accompanying text. See also *Bans, Red Ink: Smoking: A Burning Work Issue*, supra note 90 (Pacific Northwest Bell bans smoking in all facilities; Radar Electric of Seattle will not hire smokers; Capital City Products conducts seminars to help employees quit smoking).

[76] For a thorough discussion of smoking bans, see Rothstein, supra note 15, at 940.

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TESTIMONY BY VICTOR E. SCHWARTZ
PARTNER
CROWELL & MORING

BEFORE THE
ENVIRONMENTAL MATTERS COMMITTEE OF THE
MARYLAND HOUSE OF DELEGATES

TUESDAY
SEPTEMBER 7, 1993

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I. INTRODUCTION

Thank you for your kind invitation to discuss today tort law, workers' compensation, and The American With Disabilities Act of 1990 liability implications that may arise from public place exposure of Environmental Tobacco Smoke (ETS). Although I was invited to testify by The Tobacco Institute, let me make clear that the views that I am expressing today are my own and not those of any interest group. My testimony will be limited to liability issues, a topic that I have studied and practiced for the past three decades. I am not here to comment on broad social policy questions about whether this state should ban smoking in public places. In a nutshell, I will provide a limited perspective on a specific area and, hopefully, it will be of use to this Committee.

II. GENERAL

A. Tobacco Liability Background

Witnesses that you will hear from today who suggest that ETS in public places will create an avalanche of liability have predicted the same result with respect to primary smoking cases -- cases brought by smokers or their relatives against tobacco companies. Nevertheless, since the first cases were brought in the primary smoking area four decades ago, no individual has been able to recover damages. These individuals were represented by very bright and diligent attorneys. Extraordinary discovery and information gathering were a bedrock on which these cases had to rise or fall. In spite of the fact that there has been widespread

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publicity from the Surgeon General and others asserting that primary smoking is dangerous to one's health, the cases failed.

Apart from the primary smoking cases, no ETS cases have proceeded beyond preliminary phases.

It is true, as will be pointed out, that the primary smoking cases are different from ETS cases. In the primary smoking cases it can be argued that a claimant knew of the risk and voluntarily encountered it. Lawyers call this "assumption of risk." In many states, this is a good defense. In ETS cases, by way of contrast, a claimant can argue that he did not know of the claimed risk of ETS exposure or, because economic necessity compelled him to work for a living, he did not voluntarily encounter it. In some situations one could argue that a person knew of the purported risk and voluntarily encountered it, he or she could have chosen another occupation, but the basic point is that the assumption of risk defense may not prevail in all cases. Nevertheless, claimants, whether under workers' compensation or common law, face a hurdle that has not been a major one in all recent primary smoker cases, that of causation. When it comes to causation, a person who has smoked three packs of cigarettes for thirty years is in a better situation to prove causation than an individual who has been exposed to some smoke in a work place. As I will detail today, in spite of the recent EPA report classifying tobacco smoke as a "Class A" carcinogen, the causation hurdle is unlikely to be vaulted by many claimants either under the common law of torts or workers' compensation.

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III. COMMON LAW ACTION IN TORT

As I have indicated, there have been no successful actions by claimants in ETS cases. It is true such cases are new, but knowledge about potential problems with ETS has been in the literature for many years. Under the common law, the plaintiff must prove that an injury was the predicate for his harm on a "more probable than not" basis. See Maryland Civil Pattern Jury Instruction 10:1 (2d ed. 1984). It is almost impossible in common law actions, even with "lax rules" permitting marginally qualified experts to testify, to show that ETS, was the primary or principal cause of a harm. Assuming that EPA's classification of ETS as a "Group A" carcinogen is correct, all of us are exposed to many carcinogens everyday -- anyone driving a car through tunnels and through traffic breathes in Benzene (a "Class A" carcinogen under EPA rules) as well as other substances that have been identified by the EPA as causes of cancer.

For example, Chromium is found in almost all tap water. Millions of pounds are released into the air from industrial sources each year. EPA has classified Chromium as a "Class A" carcinogen.

Benso(A) Pyrene is classified by EPA as a "Class B" carcinogen. It is found in the air and also on things like roast coffee, hamburgers, and fuel from wood fires and barbecues. Formaldehyde, another "Class B" substance, can be released from office furnishings.

Also, if we are focusing on cancer, its potential causes are many, including family history, eating patterns, and other sources.

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The bottom line is that while plaintiffs who have been exposed to ETS may be more sympathetic to juries than primary smokers, it is very unlikely that they will have success under the common law of torts. Let me now focus on workers' compensation claims.

IV. WORKERS' COMPENSATION CLAIMS

It is unlikely that an employer would be held liable for workers' compensation under Maryland law for employee injuries allegedly due to ETS. Injury allegedly due to exposure to ETS is not an "accidental personal injury," because workplace smoking is not an unusual event in the daily routine of the workplace and employees are equally exposed to ETS outside of the workplace. Disease allegedly caused by workplace ETS would also fail to constitute an "occupational disease" within the meaning of the Maryland statute because ETS is not a naturally inherent condition of any employment.

A. Accidental Personal Injury

An injury allegedly caused by workplace exposure to ETS would not "arise out of the scope of employment" as defined by the Maryland courts. An injury arises out of employment when, "after consideration of the facts and circumstances of the case, it is apparent to the rational mind that there was a causal connection between the conditions under which the work is required to be performed and the ensuing injury." Blake Construction Co. v. Wells, 225 A.2d 857, 862 (Md. 1967). The causative danger must be "incidental to the nature of the business, and not independent of

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the relation of master and servant." Id. An injury caused by a "hazard to which the workman would have been equally exposed apart from his employment" is not compensable under the Maryland statute. Id.; Consolidated Engineering Co. v. Feikin, 52 A.2d 913, 916 (Md. 1947).

ETS is a condition to which an employee is equally exposed apart from his employment. Therefore, this alleged causative danger is not incidental to the nature of the work. Any resulting injury would therefore not "arise out of" an employee's employment.

An injury allegedly caused by workplace exposure to ETS is unlikely to be deemed "accidental" within the meaning of the workers' compensation statute. Unlike many other jurisdictions, Maryland has adopted a very narrow interpretation of "accident."[1/] Sargent v. Board of Education,, 433 A.2d 1209, 1211 (Md. Ct. Spec. App. 1981). In order for an injury to be "accidental," and therefore compensable, it must result from "some unusual or extraordinary condition of the employment." Stancliff v. H.B. Davis Co., 117 A.2d 577, 583 (Md. 1955) (emphasis added); Sargent, 433 A.2d at 1211. Injuries that occur without special incident, simply as a result of day-to-day working conditions, are not compensable under the workers' compensation scheme as "accidents." See Whiting-Turner Contracting Co. v. Turner, 274 A.2d 390, 394

1/ The majority of jurisdictions consider an injury to be accidental if it was the unexpected result of the routine performance of the employee's duties. Sargent, 433 A.2d at 1211. However, "Maryland law requires an accident and not merely a result." Whiting-Turner Contracting Co. v. McLaughlin, 274 A.2d 390, 394 (Md. Ct. Spec. App. 1971).

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(Md. Ct. Spec. App. 1971). Thus, where smoking is permitted in designated areas as part of the normal, daily working conditions, any injury allegedly caused by that smoking is not "accidental." Unless an employee's injuries arose on the unusual occasion of another specific worker smoking in the workplace, any injuries allegedly due to workplace exposure to ETS are unlikely to be compensable accidents.

B. Occupational Disease

Employee injuries and diseases allegedly due to workplace exposure to ETS would not be compensable under Maryland law as an "occupational disease." A compensable occupational disease is limited to "the expectable result of working under conditions naturally inherent in the employment and inseparable therefrom, and is ordinarily slow and insidious in its approach." Foble v. Knefely, 6 A.2d 48, 53 (Md. 1939); LeCompete v. United Parcel Service, Inc., 602 A.2d 261, 262 (Md. Ct. Spec. App. 1992). The state courts have emphasized that the cause of the disease must have its origin in the inherent nature or mode of work. Victory Sparkler & Specialty Co. v. Francks, 128 A. 635 (Md. 1925); LeCompte, 602 A.2d at 263. If a disease "is the consequence of some extrinsic condition or independent agency, the disease or injury" is not an occupational disease. LeCompte, 602 A.2d at 263 (citing Victory Sparkler).

ETS is not naturally inherent in any one particular employment. Instead, it is an extrinsic condition found outside of the workplace that is not inseparable from the work conditions.

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Therefore, any injuries [supposedly] caused by ETS are not compensable occupational diseases.

C. Duty to Provide a Safe Workplace

The Maryland workers' compensation law is the exclusive remedy for employee injuries that arise out of and in the course of employment. Md. Lab. & Emp. Code Ann. § 9-509. If an employee's injury is not classified as an "accidental personal injury" or an "occupational disease" within the scope of the workers' compensation statute, however, common law remedies are available. Wood v. Aetna Casualty & Surety Co., 273 A.2d 125, 131 (Md. 1971).

I have addressed the causation problem with regard to common law ETS claims earlier. This problem would face both customers of commercial establishment and employees. Employees are owed a duty of care which Maryland has codified. An employer must provide a safe workplace. See Md. Lab. & Emp. Code Ann. § 5-104. This general statutory duty requires an employer to provide a safe and healthful work environment and to keep the workplace free from recognized hazards that cause or are likely to cause death or serious physical harm to the employee. Id. § 5-104(a)(1)&(2). The courts have interpreted this statute to require an employer to take "reasonable precautionary steps to protect its employees from reasonably foreseeable recognized danger." Mardo Homes, Inc. v. Commissioner of Labor and Industry, 370 A.2d 144 (Md. Ct. Spec. App. 1977).

This statutory duty would not require an employer to impose a smoking ban in the workplace. The statute merely requires employers to take "reasonable precautionary steps," which the

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overwhelming majority of the employers have already done. Thus, steps such as separating smokers and non-smokers into designated smoking areas, proper ventilation, and handling specific complaints of hypersensitive workers should satisfy the statutory duty.

V. THE AMERICANS WITH DISABILITIES ACT OF 1990

A few individuals claiming special sensitivity to tobacco smoke have claimed that The Americans With Disabilities Act of 1990 (the ADA), 42 U.S.C. 12101 et seq. (Supp. 1992), requires the imposition of smoking bans or severe restrictions in various public and private facilities. This assertion is incorrect. First, nothing on the ADA's face mandates the imposition of any smoking policy whatsoever on covered entities. Second, even if an individual could establish that he was "hypersensitive" to tobacco smoke and thus "disabled" within the meaning of the ADA (which would be extremely difficult), a covered facility need only make a "reasonable accommodation" of that individual's needs. Such reasonable accommodation does not require the imposition of total bans on smoking or other severe restrictions by employers or by government.

VI. CONCLUSION

No expert or layperson can predict with absolute certainty whether any claimant in ETS cases under the common law of torts, workers' compensation or The American With Disabilities Act of 1990 will ever be able to prevail in a case. Our liability

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system, as I have suggested in other contexts, is filled with uncertainties. But this much is relatively certain, there will not be an avalanche of successful ETS liability claims. The liability hurdles that I have outlined today are not going to fall. Cases prevail where issues of fault, causation and duty are relatively clear. In spite of the EPA Report and other information sources, the ETS liability situation remains muddled at best. If policymakers are to ban smoking in public places or not, their focus should be on factors other than the liability system -- it is an irrelevant factor, one way or the other, in making this important decision.

Again, I appreciate the opportunity to talk with you today.

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VICTOR E. SCHWARTZ

BIOGRAPHICAL SKETCH

Victor E. Schwartz received his Bachelor of Arts degree (History) from Boston University, Summa Cum Laude and his Juris Doctor from Columbia University, Magna Cum Laude. He was an editor of the Columbia Law Review and received numerous awards for his scholarship. He served as law clerk to a Federal judge. He was a member of the faculty at the University of Cincinnati College of Law and practiced law in the State of Ohio. He served as Acting Dean and has continued his association with the school as an Adjunct Professor.

After leaving Cincinnati, he chaired the Federal Interagency Task Force on Product Liability and received the Secretary of Commerce's Special Medal for his efforts. He drafted the Uniform Product Liability Act which has been the basis for most state product liability legislation. He chaired the Federal Interagency Council on Insurance, which coordinated all insurance policy issues within the Federal Government. He developed the Risk Retention Act which facilitates commercial self-insurance for small businesses, and it has been enacted into law.

Since 1980, Mr. Schwartz has been a partner in the Washington, D.C. law firm of Crowell & Moring. He co-chairs the firm's Torts and Insurance Practice Group. His practice involves litigation, the development of legislation and product liability loss prevention. He is also an Adjunct Professor at Georgetown University Law Center.

Mr. Schwartz has chaired the Products, General Liability and Consumer law Committee of the American Bar Association; the Torts Section of the Association of American Law Schools, and serves on the Product Safety & Liability Reporter Board of Advisors. He is a member of the American Law Institute and was recently appointed to the Advisory Committee of the Restatement of Torts (Third): Products Liability project. He currently chairs the Civil Justice Reform Committee of the American Legislative Exchange Council and the Legislative Committee of the ABA Litigation Section. He is a Director of the American Tort Reform Association.

He is co-author of the most widely used torts casebook in the United States, Prosser, Wade and Schwartz, Cases and Materials on Torts. The text has sold over 300,000 copies. He is author of the leading treatise on the topic of Comparative Negligence and co-author of a treatise on Multistate Litigation. His written works have frequently been cited by state Supreme and Federal courts throughout the United States.

In light of these accomplishments, The National Journal has named Mr. Schwartz one of the 15 attorneys in the United States who make a difference in the formulation of public policy.

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